



**Laboratorios Conda S.A - SUPLEMENTO CCDA
(SUPLEMENTO PARA CAMPYLIBACTER) - CCDA
SUPPLEMENT (CAMPYLOBACTER SUPPLEMENT)
6053**

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

- 1.1 Product identifier:** Laboratorios Conda S.A - SUPLEMENTO CCDA (SUPLEMENTO PARA CAMPYLIBACTER) - CCDA SUPPLEMENT (CAMPYLOBACTER SUPPLEMENT) 6053
- Other means of identification:**
Non-applicable
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses: Culture medium. For professional users only.
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:**
Laboratorios Conda S.A
C/ La Forja, Nº 9
28850 Torrejón de Ardoz - Madrid - Spain
Phone: +34 761 02 00 - Fax: 916568228
www.condalab.com
- 1.4 Emergency telephone number:** Centro Nacional de Toxicología. Horario continuado 24 horas. Teléfono de contacto: +34 915620420

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture:**
CLP Regulation (EC) No 1272/2008:
Classification of this product has been carried out in accordance with CLP Regulation (EC) No 1272/2008.
Eye Irrit. 2: Eye irritation, Category 2, H319
Resp. Sens. 1: Sensitisation, respiratory, Category 1, H334
Skin Irrit. 2: Skin irritation, Category 2, H315
Skin Sens. 1: Sensitisation, skin, Category 1, H317
STOT SE 3: Respiratory tract toxicity, single exposure, Category 3, H335
- 2.2 Label elements:**
CLP Regulation (EC) No 1272/2008:
Danger
-  
- Hazard statements:**
Eye Irrit. 2: H319 - Causes serious eye irritation.
Resp. Sens. 1: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin Irrit. 2: H315 - Causes skin irritation.
Skin Sens. 1: H317 - May cause an allergic skin reaction.
STOT SE 3: H335 - May cause respiratory irritation.
- Precautionary statements:**
P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
P280: Wear protective gloves/protective clothing/respiratory protection/eye protection/protective footwear.
P285: In case of inadequate ventilation wear respiratory protection.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P501: Dispose of the contents/containers in accordance with the current legislation on waste treatment
- Substances that contribute to the classification**
Amphotericin B (CAS: 1397-89-3); 5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[[(4-ethyl-2,3-dioxo-1-piperazinyl)carbonyl]amino](4-hydroxyphenyl)acetyl]amino]-3-[[[(1-methyl-1H-tetrazol-5-yl)thio]methyl]-8-oxo-, monosodium salt, [6R-[6 α ,7 β (R*)]] (CAS: 62893-20-3)

- CONTINUED ON NEXT PAGE -

**Laboratorios Conda S.A - SUPLEMENTO CCDA
(SUPLEMENTO PARA CAMPYLIBACTER) - CCDA
SUPPLEMENT (CAMPYLOBACTER SUPPLEMENT)
6053**

SECTION 2: HAZARDS IDENTIFICATION (continued)

2.3 Other hazards:

Product fails to meet PBT/vPvB criteria
Endocrine-disrupting properties: The product fails to meet the criteria.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS **

3.1 Substance:

Non-applicable

3.2 Mixture:

Chemical description: Mixture of substances

Components:

In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 1397-89-3 EC: 215-742-2 Index: Non-applicable REACH: Non-applicable	Amphotericin B <input type="checkbox"/> ¹ <input type="checkbox"/> Regulation 1272/2008 Eye Irrit. 2: H319; Skin Irrit. 2: H315; STOT SE 3: H335 - Warning	Self-classified 75 - <100 %
CAS: 62893-20-3 EC: 263-751-5 Index: Non-applicable REACH: Non-applicable	5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[[(4-ethyl-2,3-dioxo-1-piperazinyl)carbonyl]amino](4-hydroxyphenyl)acetyl]amino]-3-[[[(1-methyl-1H-tetrazol-5-yl)thio]methyl]-8-oxo-, monosodium salt, [6R-[6α,7β(R*)]] <input type="checkbox"/> ¹ <input type="checkbox"/> Regulation 1272/2008 Resp. Sens. 1: H334; Skin Sens. 1: H317 - Danger	Self-classified 2 - <10 %

¹ Voluntarily-listed substance failing to meet any of the criteria set out in Regulation (EU) No. 2020/878

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

** Changes with regards to the previous version

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

Remove the person affected from the area of exposure, provide with fresh air and keep at rest. In serious cases such as cardiorespiratory failure, artificial resuscitation techniques will be necessary (mouth to mouth resuscitation, cardiac massage, oxygen supply, etc.) requiring immediate medical assistance.

By skin contact:

Remove contaminated clothing and footwear, rinse skin or shower the person affected if appropriate with plenty of cold water and neutral soap. In serious cases see a doctor. If the product causes burns or freezing, clothing should not be removed as this could worsen the injury caused if it is stuck to the skin. If blisters form on the skin, these should never be burst as this will increase the risk of infection.

By eye contact:

Rinse eyes thoroughly with lukewarm water for at least 15 minutes. Do not allow the person affected to rub or close their eyes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

By ingestion/aspiration:

Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

4.2 Most important symptoms and effects, both acute and delayed:

- CONTINUED ON NEXT PAGE -

**Laboratorios Conda S.A - SUPLEMENTO CCDA
(SUPLEMENTO PARA CAMPYLIBACTER) - CCDA
SUPPLEMENT (CAMPYLOBACTER SUPPLEMENT)
6053**

SECTION 4: FIRST AID MEASURES (continued)

Acute and delayed effects are indicated in sections 2 and 11.

4.3 Indication of any immediate medical attention and special treatment needed:

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems.

Unsuitable extinguishing media:

Non-applicable

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel:

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

For emergency responders:

See section 8.

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.-Precautions for safe manipulation

- CONTINUED ON NEXT PAGE -

**Laboratorios Conda S.A - SUPLEMENTO CCDA
(SUPLEMENTO PARA CAMPYLIBACTER) - CCDA
SUPPLEMENT (CAMPYLOBACTER SUPPLEMENT)
6053**

SECTION 7: HANDLING AND STORAGE (continued)

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

Due to its inflammable nature, the product does not present a fire risk under normal conditions of storage, handling and use.

C.- Technical recommendations to prevent ergonomic and toxicological risks

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Store in a cool, dry, well-ventilated location

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace (European OEL, not country-specific legislation):



Nuisance dust: Inhalable dust 10 mg/m³ // Respirable dust 4 mg/m³

8.2 Exposure controls:



A.- Individual protection measures, such as personal protective equipment

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Regulation (EU) 2016/425. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory respiratory tract protection	Filter mask for gases and vapours		EN 405:2002+A1:2010	Replace when there is a taste or smell of the contaminant inside the face mask. If the contaminant comes with warnings it is recommended to use isolation equipment.

C.- Specific protection for the hands

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	Protective gloves against minor risks			Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional users/industrials, we recommend using CE III gloves in line with standards EN 420:2004 +A1:2010 and EN ISO 374-1:2016+A1:2018



- CONTINUED ON NEXT PAGE -

**Laboratorios Conda S.A - SUPLEMENTO CCDA
(SUPLEMENTO PARA CAMPYLIBACTER) - CCDA
SUPPLEMENT (CAMPYLOBACTER SUPPLEMENT)
6053**



SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

As the product is a mixture of several substances, the resistance of the glove material can not be calculated in advance with total reliability and has therefore to be checked prior to the application.



D.-Ocular and facial protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Panoramic glasses against splash/projections.		EN 166:2002 EN ISO 4007:2018	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.

E.- Body protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing			Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 6529:2013, EN ISO 6530:2005, EN ISO 13688:2013, EN 464:1994.
	Anti-slip work shoes		EN ISO 20347:2012	Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 20345:2012 y EN 13832-1:2007

F.- Additional emergency measures

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011	 Eyewash stations	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C: Solid
 Appearance: Characteristic
 Colour: Characteristic
 Odour: Characteristic
 Odour threshold: Non-applicable *

Volatility:

Boiling point at atmospheric pressure: Non-applicable *
 Vapour pressure at 20 °C: Non-applicable *
 Vapour pressure at 50 °C: Non-applicable *
 Evaporation rate at 20 °C: Non-applicable *

Product description:

*Not relevant due to the nature of the product, not providing information property of its hazards.

- CONTINUED ON NEXT PAGE -

**Laboratorios Conda S.A - SUPLEMENTO CCDA
(SUPLEMENTO PARA CAMPYLIBACTER) - CCDA
SUPPLEMENT (CAMPYLOBACTER SUPPLEMENT)
6053**

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Density at 20 °C:	Non-applicable *
Relative density at 20 °C:	Non-applicable *
Dynamic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 40 °C:	Non-applicable *
Concentration:	Non-applicable *
pH:	Non-applicable *
Vapour density at 20 °C:	Non-applicable *
Partition coefficient n-octanol/water 20 °C:	Non-applicable *
Solubility in water at 20 °C:	Non-applicable *
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *
Flammability:	
Flash Point:	Non-applicable
Flammability (solid, gas):	Non-applicable *
Autoignition temperature:	Non-applicable *
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *
Explosive (Solid):	
Lower explosive limit:	Non-applicable *
Upper explosive limit:	Non-applicable *
Particle characteristics:	
Median equivalent diameter:	Non-applicable *

9.2 Other information:

Information with regard to physical hazard classes:

Explosive properties:	Non-applicable *
Oxidising properties:	Non-applicable *
Corrosive to metals:	Non-applicable *
Heat of combustion:	Non-applicable *
Aerosols-total percentage (by mass) of flammable components:	Non-applicable *

Other safety characteristics:

Surface tension at 20 °C:	Non-applicable *
Refraction index:	Non-applicable *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7.

10.2 Chemical stability:

Chemically stable under the conditions of storage, handling and use.

- CONTINUED ON NEXT PAGE -

**Laboratorios Conda S.A - SUPLEMENTO CCDA
(SUPLEMENTO PARA CAMPYLIBACTER) - CCDA
SUPPLEMENT (CAMPYLOBACTER SUPPLEMENT)
6053**

SECTION 10: STABILITY AND REACTIVITY (continued)

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Not applicable	Not applicable	Avoid alkalis or strong bases

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION **

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

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

A- Ingestion (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for consumption. For more information see section 3.
- Corrosivity/Irritability: The consumption of a considerable dose can cause irritation in the throat, abdominal pain, nausea and vomiting.

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Causes irritation in respiratory passages, which is normally reversible and limited to the upper respiratory passages.

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Produces skin inflammation.
- Contact with the eyes: Produces eye damage after contact.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for the effects mentioned. For more information see section 3.
IARC: Non-applicable
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

E- Sensitizing effects:

- Respiratory: Prolonged exposure can result in specific respiratory hypersensitivity.
- Cutaneous: Prolonged contact with the skin can result in episodes of allergic contact dermatitis.

F- Specific target organ toxicity (STOT) - single exposure:

** Changes with regards to the previous version

- CONTINUED ON NEXT PAGE -

**Laboratorios Conda S.A - SUPLEMENTO CCDA
(SUPLEMENTO PARA CAMPYLIBACTER) - CCDA
SUPPLEMENT (CAMPYLOBACTER SUPPLEMENT)
6053**

SECTION 11: TOXICOLOGICAL INFORMATION ** (continued)

Causes irritation in respiratory passages, which is normally reversible and limited to the upper respiratory passages.

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

Other information:

Non-applicable

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[[(4-ethyl-2,3-dioxo-1-piperazinyl)carbonyl]amino](4-hydroxyphenyl)acetyl]amino]-3-[[[(1-methyl-1H-tetrazol-5-yl)thio]methyl]-8-oxo-, monosodium salt, [6R-[6α,7β(R*)]] CAS: 62893-20-3 EC: 263-751-5	LD50 oral	12000 mg/kg	Rat
	LD50 dermal	Non-applicable	
	LC50 inhalation	Non-applicable	

11.2 Information on other hazards:

Endocrine disrupting properties

Endocrine-disrupting properties: The product fails to meet the criteria.

Other information

Non-applicable

** Changes with regards to the previous version

SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

12.1 Toxicity:

- CONTINUED ON NEXT PAGE -

**Laboratorios Conda S.A - SUPLEMENTO CCDA
(SUPLEMENTO PARA CAMPYLIBACTER) - CCDA
SUPPLEMENT (CAMPYLOBACTER SUPPLEMENT)
6053**

SECTION 12: ECOLOGICAL INFORMATION (continued)

Not available

12.2 Persistence and degradability:

Not available

12.3 Bioaccumulative potential:

Not available

12.4 Mobility in soil:

Not available

12.5 Results of PBT and vPvB assessment:

Product fails to meet PBT/vPvB criteria

12.6 Endocrine disrupting properties:

Endocrine-disrupting properties: The product fails to meet the criteria.

12.7 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
16 05 06*	laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals	Dangerous

Type of waste (Regulation (EU) No 1357/2014):

HP5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity, HP4 Irritant – skin irritation and eye damage

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommended disposal down the drain. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

Transport of dangerous goods by land:

With regard to ADR 2021 and RID 2021:

- CONTINUED ON NEXT PAGE -

**Laboratorios Conda S.A - SUPLEMENTO CCDA
(SUPLEMENTO PARA CAMPYLIBACTER) - CCDA
SUPPLEMENT (CAMPYLOBACTER SUPPLEMENT)
6053**

SECTION 14: TRANSPORT INFORMATION (continued)

14.1 UN number or ID number: Non-applicable

14.2 UN proper shipping name: Non-applicable

14.3 Transport hazard class (es): Non-applicable

Labels: Non-applicable

14.4 Packing group: Non-applicable

14.5 Environmental hazards: No

14.6 Special precautions for user

Special regulations: Non-applicable

Tunnel restriction code: Non-applicable

Physico-Chemical properties: see section 9

Limited quantities: Non-applicable

14.7 Maritime transport in bulk according to IMO instruments: Non-applicable

Transport of dangerous goods by sea:

With regard to IMDG 39-18:

14.1 UN number or ID number: Non-applicable

14.2 UN proper shipping name: Non-applicable

14.3 Transport hazard class (es): Non-applicable

Labels: Non-applicable

14.4 Packing group: Non-applicable

14.5 Marine pollutant: No

14.6 Special precautions for user

Special regulations: Non-applicable

EmS Codes:

Physico-Chemical properties: see section 9

Limited quantities: Non-applicable

Segregation group: Non-applicable

14.7 Maritime transport in bulk according to IMO instruments: Non-applicable

Transport of dangerous goods by air:

With regard to IATA/ICAO 2022:

14.1 UN number or ID number: Non-applicable

14.2 UN proper shipping name: Non-applicable

14.3 Transport hazard class (es): Non-applicable

Labels: Non-applicable

14.4 Packing group: Non-applicable

14.5 Environmental hazards: No

14.6 Special precautions for user

Physico-Chemical properties: see section 9

14.7 Maritime transport in bulk according to IMO instruments: Non-applicable

SECTION 15: REGULATORY INFORMATION

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

- CONTINUED ON NEXT PAGE -

**Laboratorios Conda S.A - SUPLEMENTO CCDA
(SUPLEMENTO PARA CAMPYLIBACTER) - CCDA
SUPPLEMENT (CAMPYLOBACTER SUPPLEMENT)
6053**

SECTION 15: REGULATORY INFORMATION (continued)

Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Non-applicable
Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable
Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: Non-applicable
Article 95, REGULATION (EU) No 528/2012: Non-applicable
REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

Seveso III:

Non-applicable

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc):

Non-applicable

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION**Legislation related to safety data sheets:**

The SDS shall be supplied in an official language of the country where the product is placed on the market. This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (COMMISSION REGULATION (EU) 2020/878).

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

COMMISSION REGULATION (EU) 2020/878

COMPOSITION/INFORMATION ON INGREDIENTS (SECTION 3, SECTION 11):

· New declared substances

5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[[(4-ethyl-2,3-dioxo-1-piperazinyl)carbonyl]amino](4-hydroxyphenyl)acetyl]amino]-3-[[[(1-methyl-1H-tetrazol-5-yl)thio]methyl]-8-oxo-, monosodium salt, [6R-[6 α ,7 β (R*)]] (62893-20-3)

Texts of the legislative phrases mentioned in section 2:

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H317: May cause an allergic skin reaction.

H315: Causes skin irritation.

H335: May cause respiratory irritation.

H319: Causes serious eye irritation.

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008:

Eye Irrit. 2: H319 - Causes serious eye irritation.

Resp. Sens. 1: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin Irrit. 2: H315 - Causes skin irritation.

Skin Sens. 1: H317 - May cause an allergic skin reaction.

STOT SE 3: H335 - May cause respiratory irritation.

Classification procedure:

- CONTINUED ON NEXT PAGE -

**Laboratorios Conda S.A - SUPLEMENTO CCDA
(SUPLEMENTO PARA CAMPYLIBACTER) - CCDA
SUPPLEMENT (CAMPYLOBACTER SUPPLEMENT)
6053**

SECTION 16: OTHER INFORMATION (continued)

Resp. Sens. 1: Calculation method

Skin Sens. 1: Calculation method

Skin Irrit. 2: Calculation method

STOT SE 3: Calculation method

Eye Irrit. 2: Calculation method

Advice related to training:

Minimal training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50

EC50: Effective concentration 50

LogPOW: Octanolwater partition coefficient

Koc: Partition coefficient of organic carbon

UFI: unique formula identifier

IARC: International Agency for Research on Cancer

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -