

# ACEF S.p.A.

Revision nr.12 Dated 27/07/2023 Printed on 27/07/2023 Page n. 1 / 10 Replaced revision:11 (Dated 10/12/2020)

004766 - L-5-HYDROXY-TRYPTOPHAN

# **Safety Data Sheet**

According to Annex II to REACH - Regulation (EU) 2020/878 and to Annex II to UK REACH

### SECTION 1. Identification of the substance/mixture and of the company/undertaking

Code: Product name Chemical name and synonym EC number CAS number 004766 L-5-HYDROXY-TRYPTOPHAN 5-HTP 224-411-1 4350-09-8

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

Intended use

raw material for cosmetic product.

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

Name	ACEF S.p	).A.		
Full address	Via Umbr	ia 8/14		
District and Country	29017	FIORENZUOLA D"ARDA	(PC)	
		Italia		
	Tel.	+39 0523 241911		
	Fax	+39 0523 241929 - 241968		
e-mail address of the competent person				
responsible for the Safety Data Sheet	sicurezza	@pec.acef.it		
1.4. Emergency telephone number				
For urgent inquiries refer to	Centro Antiveleni, Policlinico "Umberto I", Tossicologia d'urgenza, Roma - Tel. +39 06-49978000			
	Centro Antiveleni, Az. Osp. Niguarda Cà Grande, Milano - Tel. +39 02-66101029 Centro Antiveleni, Az. Osp. "Antonio Cardarelli", Napoli - Tel. +39 081-5453333 Centro Antiveleni, Az. Osp. "Papa Giovanni XXIII", Bergamo - Tel. 800883300 Centro Antiveleni, IRCCS Fondazione Salvatore Maugeri, Pavia - Tel. +39		Grande, Milano - Tel, +39 02-66101029	
			•	
	0382-244			
			Tossicologia medica, Firenze - Tel. +39	
	055-7947			
1	- ·			

Centro antiveleni del Policlinico "Agostino Gemelli", Roma - Tel. +39 06-3054343 Centro Antiveleni, Az. Osp. Foggia - Tel. 800183459

Centro Antiveleni, Ospedale pediatrico Bambino Gesù, Roma; Tel. +39 06-68593726 Centro Antiveleni dell'Az. Osp. universitaria integrata (AOUI) di Verona, Verona -Tel. 800011858

#### **SECTION 2. Hazards identification**

#### 2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.

Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication: Acute toxicity, category 3

H301

Toxic if swallowed.



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### SECTION 2. Hazards identification .../>>

#### 2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

Signal words:	Danger
Hazard statements: H301	Toxic if swallowed.
Precautionary statements	:
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P301+P310	IF SWALLOWED: immediately call a POISON CENTER / doctor /
P405	Store locked up.
P501	Dispose of contents / container to in conformity with local laws.
P330	Rinse mouth.
P321	Specific treatment (see on this label).
Contains:	L-5-HYDROXY-TRYPTOPHAN
Nr. EC:	224-411-1

#### 2.3. Other hazards

The substance does not have persistence, bioaccumulation and toxicity (PBT) properties and is not very persistent and very bioaccumulative. (vPvB).

The substance does not have endocrine disrupting properties.

# **SECTION 3. Composition/information on ingredients**

#### 3.1. Substances

Contains:			
Identificatio	on	Conc. %	Classification (EC) 1272/2008 (CLP)
<b>L-5-HYDR</b> INDEX EC CAS	OXY-TRYPTOPHAN 224-411-1 4350-09-8	100	Acute Tox. 3 H301 LD50 Oral: 243 mg/kg

The full wording of hazard (H) phrases is given in section 16 of the sheet.

# **SECTION 4. First aid measures**

#### 4.1. Description of first aid measures

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention immediately. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately. INGESTION: Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.



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#### SECTION 4. First aid measures ... / >>

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

Information not available

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

Information not available

# **SECTION 5. Firefighting measures**

#### 5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray. UNSUITABLE EXTINGUISHING EQUIPMENT None in particular.

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

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE Do not breathe combustion products.

#### 5.3. Advice for firefighters

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations. SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

## SECTION 6. Accidental release measures

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

If there are no contraindications, spray powder with water to prevent the formation of dust. Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

#### 6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

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

Collect the leaked product and place it in containers for recovery or disposal. If there are no contraindications, use jets of water to eliminate product residues.

Make sure the leakage site is well aired. Evaluate the compatibility of the container to be used, by checking section 10. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

#### 6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

### **SECTION 7. Handling and storage**

#### 7.1. Precautions for safe handling

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

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

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.



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#### SECTION 7. Handling and storage .../>>

Non esporre a temperature elevate.

- Pressione ambientale: Non è prevista alcuna procedura di restrizione.
- Temperatura: Conservare nel contenitore originale ben chiuso a temperatura ambiente (15 ° 30 ° C), in un luogo asciutto.
- Luce del sole: Non esporre alla luce diretta del sole.
- Umidità: Non conservare in un luogo umido, perché la sostanza è igroscopica.
- Vibrazione: Non è prevista alcuna procedura di restrizione.

#### 7.3. Specific end use(s)

Information not available

# **SECTION 8. Exposure controls/personal protection**

#### 8.1. Control parameters

Information not available

#### 8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

HAND PROTECTION

In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374). Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity

reactions. SKIN PROTECTION

Wear category I professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.

RESPIRATORY PROTECTION

None required, unless indicated otherwise in the chemical risk assessment.

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

# **SECTION 9.** Physical and chemical properties

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

Properties Appearance Colour Odour Melting point / freezing point Initial boiling point Flammability Lower explosive limit Upper explosive limit Flash point Auto-ignition temperature Decomposition temperature pH Kinematic viscosity Solubility Partition coefficient: n-octanol/water Vapour pressure Density and/or relative density Relative vapour density Particle characteristics	>	Value powder white or almost white odourless 270 °C 520,6 °C not available not available 268,7 °C not available 268,7 °C not available 6 not available 6 not available -1,70 not available 0,902 not available not available not available not available	Information



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# SECTION 9. Physical and chemical properties ..../>>

#### 9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

Molecular weight g/mol Explosive properties Oxidising properties 220,22 not available not available

# **SECTION 10. Stability and reactivity**

#### 10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

#### 10.2. Chemical stability

The product is stable in normal conditions of use and storage.

#### 10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

#### 10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

#### 10.5. Incompatible materials

Information not available

#### 10.6. Hazardous decomposition products

Information not available

### **SECTION 11. Toxicological information**

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

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

#### ACUTE TOXICITY

L-5-HYDROXY-TRYPTOPHAN LD50 (Oral): Acute toxicity, category 3. Toxic if swallowed.

243 mg/kg rat

Orale: LD50 rat 243 mg/kg (1) LD50 mouse 1708 mg/kg (1) EN



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# SECTION 11. Toxicological information ... / >>

LD50 rabbit 285 mg/kg (1) Dermale: Not found after bibliographic research. Inalazione: Not found after bibliographic research Altre: Intravenous : LD50 rat 27 mg/kg (1) Intravenous : LD50 mouse 375 mg/kg (1) Intraperitoneal. : LD50 mouse 298 mg/kg (1) Intraperitoneal. : LD50 rat 91 mg/kg (1) Subcutaneous : LD50 mouse 418 mg/kg (1)

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

Ames test (Salmonella thypimurium): negative

#### CARCINOGENICITY

Does not meet the classification criteria for this hazard class

Non elencato in IARC, NTP e OSHA

#### REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

TDLo Oral Mouse (pregnant 7-13 day(s) 700 mg/kg TDLo Oral Mouse (pregnant 6-15 day(s) 3 gm/kg TDLo Oral Mouse (pregnant 7-13 day(s) 2100 mg/kg); TDLo Oral Rat (pregnant 6-15 day(s) 3 gm/kg TDLo Oral Rat (pregnant 7-13 day(s) 700 mg/kg

### STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

Non trovato dopo ricerca bibliografica

#### STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

Non trovato dopo ricerca bibliografica

### ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

Non trovato dopo ricerca bibliografica

#### 11.2. Information on other hazards

Based on the available data, the substance is not listed in the main European lists of potential or suspected endocrine disruptors with



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#### human health effects under evaluation.

#### **SECTION 12. Ecological information**

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

#### 12.1. Toxicity

Non trovato dopo ricerca bibliografica

#### 12.2. Persistence and degradability

Non trovato dopo ricerca bibliografica

#### 12.3. Bioaccumulative potential

L-5-HYDROXY-TRYPTOPHAN Partition coefficient: n-octanol/water

-1,7 (predicted)

#### 12.4. Mobility in soil

Non trovato dopo ricerca bibliografica

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

The substance does not have persistence, bioaccumulation and toxicity (PBT) properties and is not very persistent and very bioaccumulative. (vPvB).

#### 12.6. Endocrine disrupting properties

Non trovato dopo ricerca bibliografica

Based on the available data, the substance is not listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

#### 12.7. Other adverse effects

Information not available

### **SECTION 13. Disposal considerations**

#### 13.1. Waste treatment methods

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations. Waste transportation may be subject to ADR restrictions.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

## **SECTION 14. Transport information**

#### 14.1. UN number or ID number

ADR / RID, IMDG, IATA: 2811

#### 14.2. UN proper shipping name

ADR / RID:	TOXIC SOLID, ORGANIC, N.O.S. (L-5-HYDROXY-TRYPTOPHAN)
IMDG:	TOXIC SOLID, ORGANIC, N.O.S. (L-5-HYDROXY-TRYPTOPHAN)
IATA:	TOXIC SOLID, ORGANIC, N.O.S. (L-5-HYDROXY-TRYPTOPHAN)



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# SECTION 14. Transport information ... / >>

# 14.3. Transport hazard class(es)

ADR / RID:	Class: 6.1	Label: 6.1
IMDG:	Class: 6.1	Label: 6.1
IATA:	Class: 6.1	Label: 6.1

# 14.4. Packing group

ADR / RID, IMDG, IATA: III

# 14.5. Environmental hazards

ADR / RID:	Environmentally Hazardous

IMDG:

Marine Pollutant

NO



6

IATA:

For Air transport, environmentally hazardous mark is only mandatory for UN 3077 and UN 3082.

#### 14.6. Special precautions for user

ADR / RID:	HIN - Kemler: 60	Limited Quantities: 5 kg	Tunnel restriction code: (E)
	Special provision: 274, 614		
IMDG:	EMS: F-A, S-A	Limited Quantities: 5 kg	
IATA:	Cargo:	Maximum quantity: 200 Kg	Packaging instructions: 677
	Passengers:	Maximum quantity: 100 Kg	Packaging instructions: 670
	Special provision:	A3, A5	

#### 14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

# **SECTION 15. Regulatory information**

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

Seveso Category - Directive 2012/18/EU:

H2

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006 None

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors not applicable

Substances in Candidate List (Art. 59 REACH) On the basis of available data, the product does not contain any SVHC in percentage ≥ than 0,1%.

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012: None

Substances subject to the Rotterdam Convention: None



#### SECTION 15. Regulatory information ... / >>

Substances subject to the Stockholm Convention:

None

#### Healthcare controls

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

#### 15.2. Chemical safety assessment

Has not been performed / is not yet available a chemical safety assessment for the substance.

# **SECTION 16.** Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Acute Tox. 3Acute toxicity, category 3H301Toxic if swallowed.

#### LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

#### GENERAL BIBLIOGRAPHY

- 1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
- 2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
- 3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
- 4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
- 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
- 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
- 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
- 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
- 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
- 10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
- 11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
- 12. Regulation (EU) 2016/1179 (IX Atp. CLP)
- 13. Regulation (EU) 2017/776 (X Atp. CLP)
- 14. Regulation (EU) 2018/669 (XI Atp. CLP)
- 15. Regulation (EU) 2019/521 (XII Atp. CLP)
- 16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
- 17. Regulation (EU) 2019/1148



#### SECTION 16. Other information ... / >>

- 18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
- 19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
- 20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
- 21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP) 22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
- The Merck Index. 10th Edition
- Handling Chemical Safety
- INRS Fiche Toxicologique (toxicological sheet)
- Patty Industrial Hygiene and Toxicology
- N.I. Sax Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website

- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses. Provide appointed staff with adequate training on how to use chemical products.

#### CALCULATION METHODS FOR CLASSIFICATION

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

Changes to previous review: The following sections were modified: 02 / 03 / 09 / 11 / 12 / 14 / 15 / 16.