

Tetrahop Gold®

Safety Data Sheet

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

1.1 Product identifier **Tetrahop Gold®**

Synonyms: Reduced isomerized hop extract, 'Tetra', Tetrahydroiso-humulones, Tetrahydro-isoalpha extract, Tetrahydro-iso-alpha-acids

1.2 Relevant identified uses of the substance of mixture and uses advised against Food ingredient

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

According to Regulation (EC) 1272/2008 [CLP]:

- Skin Sensitisation Category 1
- Skin Irritation Category 2
- Eye Irritation Category 2

2.2 Label elements

According to Regulation (EC) 1272/2008 [CLP]:

- **Hazard pictogram**



- **Signal word:**

- **Warning**

- **Hazard statements**

- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation

- **Precautionary statements**

- P280: Wear protective gloves and eye protection
- P302+P352: IF ON SKIN: Wash with plenty of soap and water
- P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P333+P313: If skin irritation or rash occurs: Get medical advice/attention.

2.3 Other Hazards

None. No components are known to be PBT/vPvB or to have endocrine disrupting properties.

**SECTION 3. COMPONENTS/INFORMATION ON INGREDIENTS****3.1 Substances**

N/A

3.2 Mixtures

Name	Concentration % by weight	CAS no.	EC no.	REACH Registration	Classification according to Regulation (EC) 1272/2008 [CLP]
Potassium salts of hop tetrahydroiso- α -acids	9	92113-15-0	295-619-8	01-2120766317-48-0000	Acute Tox. 4 H302, H312 Skin Corr. 1 H314 Eye Damage 1 H318 Skin Sens. 1 H317

Note: Read-across substance iso- α -acid, potassium salt is Skin Corr. 1 as per REACH assessment, but *in vitro* assessment of the Skin Corrosion Potential of 30% m/m solution of iso- α -acid in water according to OECD Test Guideline 431 (reconstructed human epidermis (RHE) Test Method) confirms that the mixture is not corrosive to skin. See Section 2.1 for final classification of Tetrahop Gold®.

SECTION 4. FIRST AID MEASURES**4.1 Description of first aid methods:**Inhalation: Move to fresh airSkin contact: Wash skin thoroughly with soap and water. If any symptoms persist obtain medical attention.Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.Oral ingestion: Rinse mouth out with water and drink a portion of water (ca. 200ml). Vomiting may occur but should not be induced. Obtain medical attention if symptoms persist.**4.2 Most important symptoms and effects, both acute and delayed**

Skin and eye irritation. Possible rash from skin sensitisation.

4.3 Indications of any immediate medical attention and special treatments needed

No special treatments – treat symptomatically.



SECTION 5. FIREFIGHTING MEASURES

- 5.1 Extinguishing media** Water spray, carbon dioxide, dry powder, foam.
- 5.2 Special hazards arising from substance or mixture** The product is an aqueous solution and is therefore not expected to burn. No known unusual fire or explosion hazards.
- 5.3 Advice for firefighters** Wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- 6.1 Personal precautions, protective equipment and emergency procedures** Wear appropriate protective clothing – see Section 8.
- 6.2 Environmental precautions** Small amounts (<10 litres) can be safely diluted with water and flushed into the drain. Do not discharge large amounts onto the ground or into watercourses – hold for disposal, or in the case of spillages, deal with this as indicated in Section 6.3
- 6.3 Methods and materials for containment and clearing up** Contain spillage using earth, sand or other inert material. Transfer to suitable sealed container prior to disposal. Flush area with hot soapy water to remove final traces. Use adequate ventilation or a respirator if in a confined area.
- 6.4 References to other sections** See Section 8 for appropriate protective clothing. See Section 13 for disposal.

SECTION 7. HANDLING AND STORAGE

- 7.1 Precautions for safe handling** Avoid excessive contact with product. Use appropriate protective clothing as indicated in Section 8. Wash hands after use.
- 7.2 Conditions for safe storage, including any incompatibilities** Store at 15 – 25 °C (59 – 77 °F). Keep container closed. Store in original container or suitable high-grade stainless steel, low silicate glass or high-density polyethylene. Protect from light.
- 7.3 Specific end use(s)** For use as a food ingredient. It should be used in accordance with applicable legislation.



SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control Parameters Not applicable.

8.2 Exposure Controls: Engineering controls: Not required.

- **Engineering Controls** Respiratory protection: Not normally required.

- **Eye/Face Protection** Hand protection: PVC, rubber or nitrile gloves are all suitable and should be worn. Breakthrough time estimated as 150 minutes, 136 minutes and 210 minutes respectively.

- **Hand Protection**

- **Skin Protection**

- **Respiratory Protection**

Eye protection: Safety goggles.

Skin protection: Not normally required. Long-sleeved workwear recommended.

Environmental exposure controls: Not required.



SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a) Physical state	Liquid
b) Colour	Pale yellow to amber
c) Odour	Hoppy, resinous
d) Melting point/Freezing point	Not practical to measure /< 0 °C
e) Boiling point	93 - 104 °C (200 - 220 °F)
f) Flammability	Non flammable
g) Lower and upper explosion limit	Not practical to measure
h) Flash point	Not applicable due to high water content
i) Auto-ignition temperature	Not practical to measure
j) Decomposition temperature	No hazardous decomposition when used for its intended use
k) pH	8.5 - 11
l) Kinematic viscosity	2 - 10 mPas at 20 °C
m) Solubility	Miscible. Will precipitate if acidified.
n) Partition coefficient n-octanol/water (log value)	LogP _{ow} for purified active component (hop tetrahydroiso- α -acids) is 3.1 - 4.4 at pH 7
o) Vapor pressure	Vapour pressure of read-across substance hop iso- α -acids is <i>ca.</i> 9.5 x 10 ⁻⁹ Pa
p) Density [kg/m ³]	ca. 1,020 kg/m ³
q) Relative vapor density	Not practical to measure
r) Particle characteristics	Not practical to measure

9.2 Other information N/A

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity	No reactivity hazards known.
10.2 Chemical stability	Stable if stored according to Section 7.2 and 10.5
10.3 Possibility of hazardous reaction	None known
10.4 Conditions to avoid	Avoid strong oxidizing agents. Precipitation may occur on mixing with any material.
10.5 Incompatible materials	Precipitation may occur on mixing with any material.
10.6 Hazardous Decomposition Products	None known

SECTION 11. TOXICOLOGICAL INFORMATION

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

Substance contains modified hop extracts, which may be safely used in beer, e.g. in accordance with US FDA regulation 21 CFR 172.560. Toxicological information is derived from REACH registration and from the read-across substance potassium salts of hop iso- α -acids, EC 305-203-0).

- a) Acute toxicity** At concentration present, the material is not classified as hazardous. Estimated ATE values (oral, dermal) are 11100 mg/kg bw for a 9% m/m solution.
- b) Skin corrosion/irritation** Potassium salts of read-across substance hop iso- α -acids, EC 305-203-0 are classified as irritant to the skin according to OECD Guideline 439 (In vitro skin irritation). Therefore, a mixture containing 9% EC 295-619-8 will be classified as Skin Irritation Category 2.
In vitro assessment of the skin corrosion potential of 30% m/m solution in water of read-across substance EC 305-203-0 according to OECD Test Guideline 431 (reconstructed human epidermis (RHE) test method) confirms that the mixture is **not** corrosive to skin.
- c) Serious eye damage/irritation** Classified as Eye Irritation Category 2 as a precaution based on skin irritation results and based on pH 8.5 - 11 (see Section 9).
- d) Respiratory or skin sensitization** EC 295-619-8 is classified for skin sensitisation by reading across from Hop Extract (EC 232-504-3), which is classified as a skin sensitiser according to in vitro methods. EC 295-619-8 present >1% in Tetrahop Gold®, hence Tetrahop Gold® is classified as Skin Sensitisation Category 1.
The vapour pressure of EC 295-619-8 is very low: 9.5×10^{-9} Pa (estimated by EPISuite™) and therefore respiratory sensitization is not applicable.
- e) Germ cell mutagenicity** In vitro mammalian cell gene mutation assay (CHO/HGPRT Mutation Assay) on read-across substance Rho-iso-alpha acids: not mutagenic.
In vitro mammalian cell gene mutation assay (CHO/HGPRT Mutation Assay) on read-across substance hexahydro-iso-alpha acids: not mutagenic.
Bacterial Reverse Mutation Assay on read-across substance 40% iso-alpha acids: not mutagenic.
- f) Carcinogenicity** Weight of evidence indicates lack of carcinogenicity. Hop tetrahydroiso- α -acids have a history of safe use as a component of beer.
- g) Reproductive toxicity** Weight of evidence indicates lack of reproductive toxicity. History of safe use as a component of beer. Tetrahydroiso- α -acids are approved food additives for beer in the USA, under 21 CFR § 172.560.



h) STOT- single exposure	Weight of evidence indicates safety when used for its intended use. See sections (f) and (g) above.
i) STOT- repeated exposure	Weight of evidence indicates safety when used for its intended use. See sections (f) and (g) above.
j) Aspiration hazard	Not an aspiration hazard.
11.2 Information on other hazards	N/A

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity	Read across from hop extract EC 232-504-3 <ul style="list-style-type: none">- Toxicity to fish: <i>Carassius auratus</i> (goldfish) - Etude pharmacologique de l'action du lupulin et de la fleur d'organer sur le poisson. Pharmaceutica acta Helvetiae (1953) 28(7-8), pp.183-206: lowest dose causing adverse effects estimated by calculation as ca. 80 mg/l.- Toxicity to <i>Daphnia</i> and other aquatic invertebrates: Read across substance potassium salts of hop iso-α-acids EC 205-303-0: EC50 - <i>Daphnia magna</i> (Water flea) - >57 mg/l - 48 h. NOEC - <i>Daphnia magna</i> (Water flea) - 57 mg/L - 48 h.- Toxicity to freshwater algae: Read across substance potassium salts of hop iso-α-acids EC 205-303-0: ErC50 - <i>Pseudokirchneriella subcapitata</i> strain: CCAP 278/4 - >100 mg/l - 72 h. NOEC - <i>Pseudokirchneriella subcapitata</i> strain: CCAP 278/4 - >100 mg/l - 72 h.
12.2 Persistence and degradability	Ultimate biodegradation.
12.3 Bioaccumulative potential	Not expected to bioaccumulate.
12.4 Mobility in soil	Read across substance potassium salts of hop iso- α -acids EC 205-303-0: Log K_{oc} 1.7 - 1.9 (modelling by EPISuite™).
12.5 Results of PBT and vPvB assessment:	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
12.6 Endocrine disrupting properties	This substance has not been assessed as endocrine disrupting substances. We are not aware of any information indicating that hop tetrahydroiso- α -acids have endocrine disrupting properties.

12.7 Other adverse effects N/A



SECTION 13. WASTE TREATMENT METHODS

13.1 Waste treatment methods	Dispose in accordance with all applicable local and national regulations. Labels should not be removed from containers until they have been cleaned. Contaminated containers should not be treated as household waste. Containers should be cleaned using appropriate methods and then re-used or disposed of by landfill or incineration as appropriate.
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SECTION 14. TRANSPORT INFORMATION

14.1 UN-Number	Non-hazardous for transport
14.2 Proper shipping name	Non-hazardous for transport
14.3 Transport hazard class(es)	Non-hazardous for transport
14.4 Packing group	Non-hazardous for transport
14.5 Environmental hazards	Non-hazardous for transport
14.6 Special precautions for user	Non-hazardous for transport
14.7 Maritime transport in bulk according to IMO instruments	Non-hazardous for transport

SECTION 15. REGULATORY INFORMATION

15.1 Safety, health, and environmental regulations/legislation specific for the substance or mixture	Germany: Water contaminant class 1 (self assessment) according to VwVwS from May 17th 1999 appendix 3. Do not discharge onto the ground or into watercourses. Wassergefährdungsklasse: WGK1 (Selbsteinstufung): schwach wassergefährdend Gemäß Anhang 3 der Verwaltungsvorschrift wassergefährdender Stoffe (VwVwS) vom 17.05.1999 Kenn-Nr.: 6390
15.2 Chemical safety assessments	N/A – for food use

SECTION 16. OTHER INFORMATION

- a) Revision information** Updated according to EU 2020/878
- b) Abbreviations**
- CAS Chemical Abstracts Service
- CLP Classification, Labelling and Packaging Regulation (EC) no. 1272/2008
- EC European Community/Commission
- PBT Persistent, Bioaccumulative and Toxic
- REACH Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) no. 1907/2006
- vPvB very Persistent, very Bioaccumulative
- c) Key literature references and sources for data**
- REACH registration dossiers for EC 305-203-0 for EC 295-619-8
- Glove breakthrough time: estimated by using cresol breakthrough time: Massey, L.K.. (2003). Permeability Properties of Plastics and Elastomers - A Guide to Packaging and Barrier Materials (2nd Edition) - Permeation Rates . William Andrew Publishing/Plastics Design Library. Retrieved from <https://app.knovel.com/hotlink/pdf/id:kt002WPFW2/permeability-properties/permeation-rates>
- d) Method used for classification of mixtures**
- Skin Irritation Category 2: On basis of expert judgement and read-across from similar substance
 - Eye Irritation Category 2: On basis of expert judgment and read-across from similar substance
 - Skin Sensitisation Category 1: On basis of expert judgment and read-across from similar substance
- e) H statements used in Section 3**
- H302 Harmful if swallowed
- H312 Harmful in contact with skin
- H314 Causes severe skin burns and eye damage
- H317 May cause an allergic skin reaction
- H318 Causes serious eye damage
- f) Training requirements for workers** N/A

The information in this safety data sheet is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. The information in this document is based on our present knowledge and should be used only as a supplement to information already in your possession concerning this product. It does not represent any guarantee of the properties of the product. The determination of whether and under what condition the product should be used is yours to make. We do not accept any liability for loss, injury or damage that may result from its use.