











# 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 IDENTIFCATION

## 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

H315 Causes skin irritation.

statements

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

<u>Note</u>: Read-across substance iso- $\alpha$ -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- $\alpha$ -acid in water according to OECD Test Guideline 431 (reconstructed human epidermis (RHE) Test Method) confirms that the mixture is <u>not</u> 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 air

<u>Skin contact</u>: Wash skin thoroughly with soap and water. If any symptoms persist obtain medical attention.

<u>Eye contact</u>: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

<u>Oral ingestion</u>: 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

Wear appropriate protective clothing - see Section 8. 6.1 Personal

precautions, protective equipment and emergency procedures

**6.2 Environmental** Small amounts (<10 litres) can be safely diluted with water and flushed into precautions 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

See Section 8 for appropriate protective clothing. See Section 13 for disposal.

sections

# 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 highdensity 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.

**Skin Protection** 

Engineering controls: Not required. 8.2 Exposure Controls:

Respiratory protection: Not normally required. Engineering

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

**Hand Protection** minutes respectively.

Eye protection: Safety goggles. Respiratory

**Protection** Not normally required. Long-sleeved workwear Skin protection:

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

No hazardous decomposition when used for its intended use j) Decomposition temperature

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-LogP<sub>ow</sub> for purified active component (hop tetrahydroiso- $\alpha$ -acids) is 3.1 –

octanol/water (log value) 4.4 at pH 7

o) Vapor pressure Vapour pressure of read-across substance hop iso- $\alpha$ -acids is ca. 9.5 x 10<sup>-9</sup>

Pa

p) Density [kg/m<sup>3</sup>] ca.  $1,020 \text{ kg/m}^{-3}$ 

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 None known

hazardous reaction

**10.4 Conditions to avoid** Avoid strong oxidizing agents. Precipitation may occur on mixing with any

material.

10.5 Incompatible Precipitation may occur on mixing with any material.

materials

10.6 Hazardous None known

**Decomposition Products** 





## 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- $\alpha$ -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- $\alpha$ -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:  $9.5 \times 10^{-9}$  Pa (estimated by EPISuite<sup>TM</sup>) 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)

Bacterial Reverse Mutation Assay on read-across substance 40% iso-alpha

on read-across substance hexahydro-iso-alpha acids: not mutagenic.

acids: not mutagenic.

f) Carcinogenicity

Weight of evidence indicates lack of carcinogenicity. Hop tetrahydroiso- $\alpha$ -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- $\alpha$ -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

- Toxicity to fish: Carassius auratus (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 Daphnia and other aquatic invertebrates: Read across substance potassium salts of hop iso- $\alpha$ -acids EC 205-303-0: EC50 Daphnia magna (Water flea) >57 mg/l 48 h. NOEC Daphnia magna (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 Pseudokirchneriella subcapitata strain: CCAP 278/4 >100 mg/l 72 h. NOEC Pseudokirchneriella subcapitata 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- $\alpha$ -acids EC 205-303-0: Log

 $K_{oc}$  1.7 - 1.9 (modelling by EPISuite<sup>TM</sup>).

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- $\alpha$ -acids have endocrine disrupting properties.







N/A 12.7 Other adverse effects





# 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.

## SECTION 14. TRANSPORT INFORMATION

**14.1 UN-Number** Non-hazardous for transport

**14.2 Proper shipping** Non-hazardous for transport

name

**14.3 Transport hazard** 1

class(es)

Non-hazardous for transport

**14.4 Packing group** Non-hazardous for transport

14.5 Enviromental

hazards

Non-hazardous for transport

Non-hazardous for transport

14.6 Special precautions

for user

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 readacross from similar substance

• Eye Irritation Category 2: On basis of expert judgment and readacross 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.