

Safety Data Sheet (SDS)

In accordance with 1907/2006 annex II and 1272/2008
(All references to EU regulations and directives are abbreviated into only the numeric term)
Issued 2024-06-20

VERSION NUMBER 07 - REPLACES VERSION NO. 06

BIOTEK srl Via R. Farneti 8 20129 Milan Italy P.I. 10911780152

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name ORANGE

Article number E15-18 0.61 fl.oz / E5-18 0.24 fl.oz

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

Identified uses Colouring agents, pigment

1.3 Details of the supplier of the safety data sheet

Company BIOTEK srl

Via R. Farneti 8 20129 Milan

Italy

Telephone +39 02 7380144 Email info@biotek.it

1.4 Emergency telephone number

Phone number for emergencies: 999 or 112. The numbers are available 24/7.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Upon assessment, this mixture is not classified as hazardous according to 1272/2008

2.2 Label elements

Hazard pictogramNot applicableSignal wordNot applicableHazard statementNot applicable

Supplemental hazard information

EUH210 Safety data sheet available on request.

2.3 Other hazards

This product does not contain any substances that are assessed to be a PBT or a vPvB The product does not contain any substances identified as having endocrine disruptive properties in accordance with the criteria set out in (EU) 2017/2100 or (EU) 2018/605.



SECTION 3: Composition/Information on Ingredients

3.2 Mixtures

Note that the table shows known hazards of the ingredients in pure form. These hazards are reduced or eliminated when mixed or diluted, see Section 16d.

Constituent	Classification	Concentration		
ETHANOL				
CAS no: 64-17-5	Flam. Liq. 2; H225	5 - 15 %		
EC no: 200-578-6				
Index no: 603-002-00-5				
REACH: 01-2119457610-43				

Explanations to the classification and labelling of the ingredients are given in Section 16e. Official abbreviations are printed in normal font. Text in italics are specifications and/or complements used in the calculation of the classification of this mixture, see Section 16b.

SECTION 4: First aid measures

4.1 Description of first aid measures

Generally

In case of concern, or if symptoms occur, call a doctor/physician.

Upon breathing in

Fresh air and rest. If symptoms persist seek medical advice.

Upon eye contact

Rinse the eye for several minutes with lukewarm water. If irritation persists call a doctor/ophthalmologist.

Upon skin contact

Wash the skin with soap and water.

If symptoms occur, contact a physician.

Upon ingestion

Rinse nose, mouth and throat with water.

DO NOT induce vomiting.

Get medical attention if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

Upon breathing in

Breathing may cause headache, vertigo, weakness and sickness.

Upon eye contact

Irritation may occur.

Redness.

Upon skin contact

Mild irritation may occur.

Upon ingestion

Ingestion may cause nausea, vomiting and/or diarrhoea.

4.3 Indication of any immediate medical attention and special treatment needed

Symptomatic treatment.

Upon contact with a doctor, make sure to have this safety data sheet with you.



SECTION 5: Firefighting measures

5.1 Extinguishing media

Extinguish with water mist, powder, carbon dioxide or alcoholresistant foam.

5.2 Special hazards arising from the substance or mixture

In case of fire, substances hazardous to health, or substances harmful in other respects, may be dispersed.

5.3 Advice for firefighters

Protective measures to be taken with regard to other materials at the scene of the fire. In case of fire use proper breathing apparatus.

Wear full protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Keep unauthorized and unprotected people at a safe distance.

Avoid inhalation and exposure to skin and eyes.

Ensure good ventilation.

Use recommended safety equipment, see section 8.

6.2 Environmental precautions

Avoid release to drains, soil or watercourses.

Please contact involved authorities if unintended release occurs.

6.3 Methods and material for containment and cleaning up

Absorb the liquid with an inert absorbent, vermiculite, for example. Collect the material for disposal at a waste disposal facility.

Rinse clean with water.

6.4 Reference to other sections

See section 8 and 13 for personal protection equipment and disposal considerations.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Take the necessary preventive and protective measures for safe handling.

Avoid inhalation and contact with skin and eyes.

Work in order to avoid spillage. If spillage does occur, address it immediately in accordance with the directions specified in Section 6 of this safety data sheet.

Store this product separately from food items and keep it out of the reach of children and pets.

Do not eat, drink or smoke in premises where this product is handled.

Wash your hands after using the product.

Remove contaminated clothing.

Wash contaminated clothing before reuse.

Keep away from incompatible products.

Use recommended safety equipment, see section 8.

Implement appropriate engineering controls if necessary, see Section 8.



7.2 Conditions for safe storage, including any incompatibilities

The product should be stored in a manner which prevents hazards to health and the environment. Avoid exposure to humans and animals and do not discharge the product in a sensitive environment.

Take the necessary preventive and protective measures for safe storage.

Keep out of reach for children.

To be stored away from food and animal fodder and away from devices or surfaces that are in contact with those items. Store tightly, in original packaging.

Always use sealed and visibly labeled packages.

Store in dry and cool area.

Keep away from heat and sunlight.

Store in a well-ventilated space.

Do not store close to incompatible materials (see section 10.5)).

7.3 Specific end use(s)

See identified uses in Section 1.2.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.1.1 National limit values

Iron oxide, fume (as Fe)

United Kingdom (EH40/2005)

Time-weighted-average exposure limit (TWA) 5 mg/m³

Short term exposure limit (STEL) 10 mg/m3

ETHANOL

United Kingdom (EH40/2005)

Time-weighted-average exposure limit (TWA) 1000 ppm / 1920 mg/m³

DNEL ETHANOL

	Type of exposure	Route of exposure	Value
Worker	Acute Local	Inhalation	1900 mg/m³
Consumer	Chronic Systemic	Inhalation	114 mg/m³
Worker	Chronic Systemic	Dermal	343 mg/kg bw/d
Worker	Chronic Systemic	Inhalation	950 mg/m ³
Consumer	Acute Local	Inhalation	950 mg/m³
Consumer	Acute Local	Dermal	950 mg/m³
Consumer	Chronic Systemic	Orally	87 mg/kg
Consumer	Chronic Systemic	Dermal	206 mg/kg bw/d



PNEC

ETHANOL

Environmental protection target PNEC value
Fresh water 0.96 mg/l
Freshwater sediments 3.6 mg/kg
Marine water 0.79 mg/l
Marine sediments 2.9 mg/kg
Microorganisms in sewage treatment 580 mg/l
Soil (agricultural) 0.63 mg/kg

8.2 Exposure controls

The risks posed by the product or its constituents must be considered in the task specific risk assessment, in accordance with current working environment legislation. The risk assessment should be reviewed regularly and updated if necessary.

8.2.1 Appropriate engineering controls

The ventilation in the workplace must ensure an air quality that meets the requirements of the current working environment legislation. Local exhaust ventilation should be used to remove airborne contaminants at the source.

Eye/face protection

Eye protection according to standard EN166 should be worn if there is any danger of direct exposure or splashing.

Skin protection

Use suitable protective clothing.

Use protective gloves fulfilling the standard EN374 if there is a risk of direct contact.

During continuous contact use gloves with a minimum breakthrough time of at least 240 minutes, preferably over 480 minutes.

The most suitable protective glove should be chosen in consultation with the glove supplier, taking into account the risk assessment for the specific task and the properties of the chemicals involved. Note that the breakthrough time of the material is affected by the duration of the exposure, temperature conditions, abrasion, etcetera.

Based on the chemical properties of the product, the following glove materials are recommended (EN 374):.

- Chloroprene (CR).

Respiratory protection

Use appropriate respiratory protective equipment in case of insufficient ventilation.

The most appropriate respiratory protective equipment should be decided in consultation with the appointed safety representative, taking into account the risk assessment for the specific task. Based on the physical and chemical properties of the product, the following filter type(s) and/or filter combination(s) are recommended:.

– A/P2.

8.2.3 Environmental exposure controls

For limiting environmental exposure, see section 12.



SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Physical state Liquid

Form: Creamy liquid

(b) Colour orange
(c) Odour like alcohol
(d) Melting point/freezing point Not indicated

(a) Melting point/freezing point (e) Boiling point or initial boiling point and boiling range >100 °C

(f) Flammability
Not indicated
(g) Lower and upper explosion limit
Not indicated

(h) Flash point >93 °C
(i) Auto-ignition temperature Not indicated

(j) Decomposition temperature

Not indicated

(k) pH When supplied, pH is: 7.5 - 8.5 (l) Kinematic viscosity Not indicated

(m) Solubility Solubility in water: Soluble

 (n) Partition coefficient n-octanol/water (log value)
 Not indicated

 (o) Vapour pressure
 Not indicated

 (p) Density and/or relative density
 Not indicated

(p) Density and/or relative densityNot indicated(q) Relative vapour densityNot indicated(r) Particle characteristicsNot indicated

9.2 Other information

9.2.1 Information with regard to physical hazard classes

Not indicated

9.2.2 Other safety characteristics

Not indicated

SECTION 10: Stability and reactivity

10.1 Reactivity

The product contains no substances which can lead to hazardous reactions at normal use..

10.2 Chemical stability

The product is stable at normal storage and handling conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known during normal use.

10.4 Conditions to avoid

Protect from heat and direct sunlight.

10.5 Incompatible materials

Avoid contact with acids, bases, oxidizing and reducing agents.

10.6 Hazardous decomposition products

None under normal conditions.

SECTION 11: Toxicological information

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

Information on possible health hazards are based on experience and / or toxicological properties of several components in the product.



Acute toxicity

The product is not classified as acutely toxic.

ETHANOL

LD50 rabbit 24h: > 20000 mg/kg Dermally

LC50 rat 4h: 124.7 mg/L Inhalation LD50 rat 24h: 6200 mg/kg Orally

OCTANE-1,2-DIOL

LD50 rat 24h: > 2000 mg/kg Orally

Skin corrosion/irritation

The product is not classified for skin corrosion/irritation.

Serious eye damage/irritation

The product is not classified for serious eye damage/eye irritation.

Respiratory or skin sensitisation

The product is not classified as sensitising.

Germ cell mutagenicity

The product is not classified as mutagen.

Carcinogenicity

The product is not classified as carcinogenic.

Reproductive toxicity

The product is not classified as a reproductive toxicant.

STOT-single exposure

The product is not classified for specific organ toxicity after single exposure.

STOT-repeated exposure

The product is not classified for specific organ toxicity after repeated exposure.

Aspiration hazard

The product is not classified as being toxic for aspiration.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

The product does not contain any substances identified as having endocrine disruptive properties in accordance with the criteria set out in (EU) 2017/2100 or (EU) 2018/605.

11.2.2 Other information

Not indicated.



SECTION 12: Ecological information

12.1 Toxicity

The product is not to be labelled as a environmental hazard. However, it is not inconceivable that large emissions, or repeated small emissions, can have a harmful effect on the environment.

Prevent release on land, in water and drains.

ETHANOL

LC50 Rainbow trout (Oncorhynchus mykiss) 96h: 13480 mg/L

LC50 fathead minnow (Pimephales promelas) 96h: 13480 mg/L

LC50 Freshwater water flea (Daphnia magna) 48h: 5400 mg/L

EC50 Freshwater water flea (Daphnia magna) 48 h: 9268 mg/L

LC50 Ide (Leuciscus idus) 48h: 8140 mg/L

EC50 Freshwater water flea (Daphnia magna) 24h: 10800 mg/l

IC50 Algae 72h: > 10.9 mg/L

LC50 Common Bleak (Alburnus alburnus) 96h: 11000 mg/L

LC50 Rainbow trout (Oncorhynchus mykiss) 24h: 11200 mg/L

IC50 Pseudomonas (Pseudomonas putida) 16h: 6500 mg/L

12.2 Persistence and degradability

No information is available.

12.3 Bioaccumulative potential

No information is available.

12.4 Mobility in soil

No information is available.

12.5 Results of PBT and vPvB assessment

This product does not contain any substances that are assessed to be a PBT or a vPvB.

12.6 Endocrine disrupting properties

The product does not contain any substances identified as having endocrine disruptive properties in accordance with the criteria set out in (EU) 2017/2100 or (EU) 2018/605.

12.7 Other adverse effects

No known effects or hazards.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste handling of the product

Avoid discharge into sewers.

The product is not classified as hazardous waste.

Empty, rinsed packaging is sent for recycling where practicable.

See directive 2008/98/EC on waste. Observe national or regional provisions on waste management.

SECTION 14: Transport information

Where not otherwise stated the information applies to all of the UN Model Regulations, i.e. ADR (road), RID (railway), ADN (inland waterways), IMDG (sea), and ICAO (IATA) (air).

14.1 UN number or ID number

Not classified as dangerous goods

14.2 UN proper shipping name

Not applicable



14.3 Transport hazard class(es)

Not applicable

14.4 Packing group

Not applicable

14.5 Environmental hazards

Not applicable

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Not applicable

14.8 Other transport information

Not applicable

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Not indicated.

15.2 Chemical safety assessment

Assessment and chemical safety report in accordance with 1907/2006 Annex I has not yet been performed.

SECTION 16: Other information

16a. Indication of where changes have been made to the previous version of the safety data sheet Revisions of this document

This is the seventh version

16b. Legend to abbreviations and acronyms used in the safety data sheet Full texts for Hazard Class and Category Code mentioned in section 3

Flam. Liq. 2 Flammable liquids, Hazard Category 2 - Flam. Liq. 2, H225 - Highly flammable liquid and vapour

Eye Irrit. 2 Serious eye damage/eye irritation, Hazard Category 2 - Eye Irrit. 2, H319 - Causes serious eye irritation

Explanations of the abbreviations in Section 14

ADR European Agreement concerning the International Transport of Dangerous Goods by Road

RID Regulations concerning the International Transport of Dangerous Goods by Rail

IMDG International Maritime Dangerous Goods Code

ICAO International Civil Aviation Organization (ICAO, 999 University Street, Montreal, Quebec H3C 5H7, Canada)

IATA The International Air Transport Association

16c. Key literature references and sources for data

Sources for data

Primary data for the calculation of the hazards has preferentially been taken from the official European classification list, 1272/2008 Annex I, as updated to 2024-06-20.

Where such data was not available, alternative documentation used to establish the official classification was used, e.g. IUCLID (International Uniform Chemical Information Database). As a second alternative, information was used from reputable international chemical industries, and as a third alternative other available information was used, e.g. material safety data sheets from other suppliers or information from non-profit associations, where reliability of the source was assessed by expert opinion. If, in spite of this, reliable information could not be sourced, the hazards were assessed by expert opinions based on the known hazards of similar substances, and according to the principles in 1907/2006 and 1272/2008.



Full text of regulations mentioned in this safety data sheet

1907/2006 REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of

18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC,

93/67/EEC, 93/105/EC and 2000/21/EC

1272/2008 REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation

(EC) No 1907/2006

EH40/2005 EH40/2005 Workplace exposure limits

2008/98/EC DIRECTIVE 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19

November 2008 on waste and repealing certain Directives

16d. Methods of evaluating information referred to in 1272/2008 Article 9 which was used for the purpose of classification

Hazard calculation for this mixture has been performed as a cumulative assessment with the aid of expert assessments in accordance with 1272/2008 Annex I, where all available information which may be significant to establishing the hazards of the mixture was assessed together, and in accordance with 1907/2006 Annex XI.

16e. List of relevant hazard statements and/or precautionary statements Full texts for hazard statements mentioned in section 3

H225 Highly flammable liquid and vapour

H319 Causes serious eye irritation

16f. Advice on any training appropriate for workers to ensure protection of human health and the environment

Warning for misuse

Not indicated.

Other relevant information

Not indicated

Editorial information



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