

SAFETY DATA SHEET

According to Regulation (EC) no. 1907/2006

Product name: Khiriox 12/14

Valid from: 27.04.2023

Revised on: n.a.

Version: 01

Replaced Version: -

1. Identification of the substance/preparation and of the company/undertaking

1.1 Product name Khiriox 12/14 Herbal Extract (Cannabis Oil)

Synonyms THC, delta9-tetrahydrocannabinol, Dronabinol

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

Relevant identified uses:

Can be prescribed as a medicinal cannabis product by healthcare professionals

1.3 Details of the supplier of this Safety Data Sheet

Company name and address:

Pharmadrug Production GmbH
Friedrich-Barnewitz-Str.7
18119 Rostock
Germany

Telephone + 49 381 51065666

e-mail address info@pharmadrug-production.de

Website www.pharmadrug-production.de

1.4 Emergency telephone number

Emergency contact: +49 30 192 40 (Poison Control Center – Berlin, Germany)

2. Hazards identification

2.1 Classification of the substance

Classification according to Regulation (EC) No. 1272/2008 (CLP)

Acute Toxicity: Inhalation, Category 4

Acute Toxicity: Oral, Category 4

Acute Toxicity: Skin, Category 4

Toxic to reproduction, Category 2 (H361)

SAFTEY DATA SHEET

According to Regulation (EC) no. 1907/2006

Product name: Khiriox 12/14

Valid from: 27.04.2023

Revised on: n.a.

Version: 01

Replaced Version: -

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008

Pictogram



Signal

Warning

Hazard statement(s)

H302

Harmful if swallowed

H361

Suspected of damaging fertility of the unborn child.

Precautionary statement(s)

P201

Obtain special instructions before use.

P270

Do not eat, drink or smoke when using this product.

P301+310

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P308+P313

IF exposed or concerned: Get medical advice/attention.

P330

Rinse mouth

P405

Store locked up

P501

Dispose of contents/container as toxic waste.

3 Composition/information on ingredients

Active / hazardous component

trimethyl- 3-pentyl-6a,7,8,10a-tetrahydro- 6H-benzo[c]chromen-1-ol

Formula

EC no.

Tetrahydrocannabinol

625-153-6

(1%-3% w/w)

RTECS no.

C21 H30 O2

HP8225800

CAS no.

1972-08-3

IUPAC ID

(-)-(6aR,10aR)-6,6,9-

SAFTEY DATA SHEET

According to Regulation (EC) no. 1907/2006

Product name: Khiriox 12/14

Valid from: 27.04.2023

Revised on: n.a.

Version: 01

Replaced Version: -

4 First aid measures

4.1 Description of first aid measures

General

In case of accident, contact a physician or emergency room. Show this SDS to the physician in attendance.

If inhaled

Ensure fresh air. Make sure the injured is under supervision. In case of symptoms, consult a physician.

In case of skin contact

Wash skin with soap and plenty of water. In case of symptoms, consult a physician.

In case of eye contact

Keep the eye lids a part and rinse with plenty of water for 10-15 minutes. Remove contact lenses if possible. If eyes are irritated consult an ophthalmologist.

If swallowed

Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Consult a physician. Do NOT induce vomiting unless directed to do so by medical personnel.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling and/or in section 11.

4.3 Indication of any immediate medical attention and special treatment needed

No data available

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media

water spray, alcohol resistant foam, dry extinguishing powder, carbon dioxide (CO₂).

Extinguishing media which must not be used for safety reasons:

water jet

5.2 Special hazards arising from the substance or mixture

Development of hazardous combustion gases or vapors possible in the event of fire.

5.3 Advice for firefighters

Wear protective clothing. Avoid inhalation of vapors.

5.4 Further information

No data available

SAFETY DATA SHEET

According to Regulation (EC) no. 1907/2006

Product name: Khiriox 12/14

Valid from: 27.04.2023

Revised on: n.a.

Version: 01

Replaced Version: -

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid breathing vapors, mist or gas.
Ensure adequate ventilation.

6.2 Environmental precautions

Take steps to avoid release into the environment.

6.3 Methods and materials for containment and cleaning up

Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations.

6.4 A reference to other sections

For disposal, see section 13.

SAFETY DATA SHEET

According to Regulation (EC) no. 1907/2006

Product name: Khiriox 12/14

Valid from: 27.04.2023

Revised on: n.a.

Version: 01

Replaced Version: -

7. Handling and storage

7.1 Precautions for safe handling

Apply necessary security equipment and ventilation. Avoid contact with eye and mouth. Do not inhale substance/mixture. Avoid generation of vapors/aerosols. Keep away from open flames, hot surfaces and sources of ignition.

7.2 Conditions for safe storage, including incompatibilities

Keep container tightly closed in a dry and well-ventilated place. Keep away from heat and sources of ignition. Keep locked up or in an area with restrictive access. Recommended storage temperature: 2-25° C.

7.3 Specific end use(s)

A part from uses defined in Section 1.2, no specific uses are stipulated.

8. Exposure controls/personal protection

8.1 Control parameters

Components with work place control parameters

8.2 Exposure control

Appropriate engineer controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before and after breaks and at the end of work day.

Personal protective equipment

Eye/face equipment

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must comply with the specifications of Regulation (EU) 2016/425 and EN 374. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Body protection

Impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

SAFETY DATA SHEET

According to Regulation (EC) no. 1907/2006

Product name: Khiriox 12/14

Valid from: 27.04.2023

Revised on: n.a.

Version: 01

Replaced Version: -

Respiratory protection

NIOSH approved respirator, as conditions warrant.

Control of environmental exposure

Do not let substance enter drains.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

a)	Appearance	Form: Liquid (20 °C and 101,3kPa)
b)	Color	Brown
c)	Odor	No data available
d)	pH	No data available
e)	Solubility in water	0,0028 mg/mL (23 °C)
f)	Flammability or explosive point	No data available
g)	Relative density	0,95 g/ml
h)	Vapor pressure	No data available
i)	Boiling point	155°C-160°C
j)	Molar mass for THC	314,47 g/mol

9.2 Other safety information

No data available

10 Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

Avoid heat, light and flames.

10.5 Incompatible materials

Oxidizing agents.

10.6 Hazardous decomposition products

No data available

SAFETY DATA SHEET

According to Regulation (EC) no. 1907/2006

Product name: Khiriox 12/14

Valid from: 27.04.2023

Revised on: n.a.

Version: 01

Replaced Version: -

11. Toxicological information

11.1 Information on toxicological effects (THC)

Acute toxicity

LD50 Rat, oral: 666 mg/kg, LD50 Mouse, oral: 482 mg/kg, LD50 Dog, oral: >3000 mg/kg, LD50 Monkey, oral: >3150 mg/kg, LD50 Rat, intravenous: 29 mg/kg, LD50 Mouse, intravenous: 42 mg/kg, LD50 Monkey, intravenous: 125 mg/kg

Skin corrosion / irritation

No data available

Serious eye damage / eye irritation

No data available

Respiratory / skin sensitization

No data available

Gem cell mutagenicity

No data available

Carcinogenicity

No data available

Reproductive toxicity

H361 Suspected of damaging fertility or the unborn child

Specific target organ toxicity – repeated exposure

No data available

Aspiration hazard

No data available

Photo toxicity

No data available

Additional information

Repeated use can lead to tolerance development and physical dependence. Data show reproductive toxicity in test subjects. Data show possible carcinogenic effect in test subjects. Acute effects are: Dry mouth, dizziness, restlessness, increased pulse to panic.

SAFTEY DATA SHEET

According to Regulation (EC) no. 1907/2006

Product name: Khiriox 12/14

Valid from: 27.04.2023

Revised on: n.a.

Version: 01

Replaced Version: -

12. Ecological information

12.1 Toxicity

Avoid release into the environment

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Partition coefficient n-octanol/water: 6,97 (log P (o/w)). Based on partition coefficient, there is a risk of accumulation in organism.

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

13. Disposal considerations

- 13.1 Collect and dispose of waste product, in accordance with local authority guidelines, at an authorized disposal facility. Product remainders should not intrude soil or waters.

14. Transport information

14.1 UN no.

Does not meet the criteria for classification as hazardous for transport.

14.2 UN proper shipping name

Not dangerous goods.

14.3 Transport hazards classes

Does not meet the criteria for classification as hazardous for transport.

14.4 Packaging group

Not applicable

14.5 Environmental hazards

Does not meet the criteria for classification as hazardous for transport.

14.6 Special precautions for user

SAFETY DATA SHEET

According to Regulation (EC) no. 1907/2006

Product name: Khiriox 12/14

Valid from: 27.04.2023

Revised on: n.a.

Version: 01

Replaced Version: -

No data available

Transport in accordance with local and international regulations.

15. Regulatory information

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

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) (as amended)

15.2 Chemical Safety Assessment

No data available

16. Other information

16.1 Hazards and/or precautionary statements in full

Full statements are made in relevant sections.

16.2 Further information

Copyright 2023 Pharmadrug Production GmbH. License granted to make unlimited paper copies for internal use only. The above information 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 the present state of our knowledge and is applicable to the product with regards to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Pharmadrug Production GmbH and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See invoice or packing slip for additional terms and conditions of sale. For further information please contact info@pharmadrug-production.de

16.3 Changelog

n.a.