

ENHEX GTX 99.9 PH

High-Purity Triacetin manufactured according to EXCiPACT™ GMP/GDP certified processes:

A Versatile Excipient for Advanced Pharmaceutical Formulations





Overview

The production site of KLK OLEO Life Science in Duesseldorf, Germany has a 40-year long history in manufacturing high quality triacetin (glycerol triacetate) supplying various markets. Recently, KLK has taken the next step in quality by introducing a new triacetin of high purity which is manufactured according to EXCiPACT™ certified processes.

ENHEX GTX 99.9 PH is suitable for demanding pharmaceutical formulations.

Benefits

Quality

- + Purity of $\geq 99.9\%$
- + Tested according to Ph. Eur.
- + Made in Germany

Production standard

- + **EXCiPACT™ GMP/GDP** certified processes
- + ISO Class 8 filling room (IBCs, drums)

Raw materials

- + 1) Acetic acid: synthetic
- + 2) Glycerin: vegetable-derived, non-palm
- + non-GMO, kosher & halal

Function

Plasticizer for Capsules and Tablets

Used as plasticizer in both soft and hard gelatine capsules to enhance flexibility and prevent brittleness. In tablets, it helps to improve texture and durability.

Solvent for Active Ingredients

Its solubility properties make it an excellent solvent for certain active pharmaceutical ingredients and other excipients, supporting the uniform distribution of drugs in formulations.

Stabilizer in Coatings

In coating applications, triacetin serves as a stabilizer, aiding in moisture resistance and extending shelf life.

Binder

It helps to agglomerate powder particles in tablet formulations, giving the tablet structural integrity and aiding in tablet compression. It ensures that the active ingredients are held together properly, resulting in a stable and uniform dosage form.

Flavour and Fragrance Carrier

Triacetin is often used in chewable tablets or oral liquid formulations as a carrier for flavours and fragrances, given its mild taste and odor.

Humectant

Its humectant properties help to retain moisture in formulations, which can be beneficial for topical applications or formulations that require controlled moisture content.

Excerpt from the Product information sheet (PIS)

- + Nitrosamines: Total-N-nitroso content not detectable [detection limit of < 15 µg/kg (≙ppb)]
- + Periodically testing on **Heavy Metals** acc. to **ICH Q3D**

Arsenic (As) (Class 1) max. 1 mg/kg	Mercury (Hg) (Class 1) max. 0.10 mg/kg
Cadmium (Cd) (Class 1) max. 0.2 mg/kg	Nickel (Ni) (Class 2A) max. 1 mg/kg
Cobalt (Co) (Class 2A) max. 0.5 mg/kg	Vanadium (V) (Class 2A) max. 1 mg/kg
Lead (Pb) (Class 1) max. 0.5 mg/kg	

In addition, it can be confirmed that our product does not exceed the permitted parenteral concentrations of all elements listed in table A.2.2. of the guideline.

- + Microbiological status:

Total aerobic microbial count	max. 10 CFU/g
Moulds	max. 10 CFU/g
Yeasts	max. 10 CFU/g
Escherichia coli	absent in 1 g
Salmonella	absent in 25 g
Staphylococcus aureus	absent in 1 g
Pseudomonas aeruginosa	absent in 1 g
Candida albicans	absent in 1 g

- + Information on other critical contaminants acc. to regulation EC/2023/915*:

Benzo(a)pyrene	max. 1.0 µg/kg
PAH4**	max. 1 µg/kg

*section 5, point 5.1.15

** sum of Benzo(a)pyrene, Benz(a)anthracene, Benzo(b)fluoranthene, Chrysene

- + Further Information available upon request in our **Product Information Sheet (PIS) & Technical Data Sheet (TDS)**

Packaging

- + 235 kg steel Drums, packed on pallets
- + Road tanker / iso tank
- + 1000 kg IBC, foodcert ISO 22000, DIN 150

Excipients

Derived from **Nature**
Driven by **Innovation**



Quality at KLK OLEO

- | | | | |
|------------------------|-------------|----------|------------|
| + EXCiPACT™
GMP/GDP | + ISO 14001 | + KOSHER | + RSPO |
| + ISO 9001 | + ISO 45001 | + HALAL | + EcoVadis |
| | + ISO 50001 | | |

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Manufacturing Site Switzerland

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Manufacturing Site The Netherlands

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KLK OLEO Life Science represents the strategic cooperation between KLK EMMERICH GmbH, Kolb Distribution Ltd., and KLK Kolb Specialities B.V. to offer innovative solutions in the field of life science.

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