



成都锦泰和医药化学技术有限公司

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KING-TIGER® Natural Astragalus Extract

Non-ETO

ETO Basic Information



ETO(Ethylene oxide) is an organic compound with the formula C_2H_4O . It is a cyclic ether and the simplest epoxide: a three-membered ring consisting of one oxygen atom and two carbon atoms. It is a colorless and flammable gas with a faintly sweet odor. Because it is a strained ring, ETO easily participates in a number of addition reactions that result in ring-opening. So it could combine with bacterial protein molecules, hydroxyl, carboxyl group in enzymes, nucleic acid, produce alkylation effect, irreversible destruction of the metabolism of bacterial cells, so as to achieve sterilization effect.¹

ETO Toxicity

ETO toxicity has been established in a variety of animals.



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Exposure to ETO can cause eye pain, sore throat, difficulty breathing and blurred vision. Exposure can also cause dizziness, nausea, headache, convulsions, blisters and vomiting and coughing.² In a variety of in vitro and animal studies, ETO has been demonstrated to be carcinogenic. ETO has been linked to spontaneous abortion, genetic damage, nerve damage, peripheral paralysis, muscle weakness, and impaired thinking and memory.²

Relevant Regulations

ETO is highly toxic.

The placing on the market and use of ETO as a component in **plant protection products** are prohibited under Regulation (EC) No 1107/2009. The making available on the market and use of ETO as a component in **biocidal products** in accordance with Regulation (EU) No 528/2012 are only allowed with regard to certain products pursuant to Commission Delegated Regulation (EU) No 1062/2014.

According to Regulations (EC) No 1223/2009, ETO is prohibited



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in **cosmetic products.**

According to the European Medicines Agency sterilisation guideline, ETO sterilisation is generally only acceptable if no other method of sterilisation is possible. Residual genotoxic impurities (for instance ETO and halogenated ethylenehydrides) should be evaluated in accordance with the requirements of ICH M7, unless the product is outside the scope of that guideline. For products outside the scope of ICH M7 the limits below apply.

Material	Ethylene oxide	Ethylene chlorhydrin (or any other halogenated ethylenehydride)
Raw materials	1 µg/g	50 µg/g
Finished product (when used on the finished product)	1 µg/g	50 µg/g
Container (based on simulated use)	1 µg/ml	50 µg/ml

KT® Natural Astragalus Extract

Chengdu King-tiger, not only pay attention to product content, but also pay more attention to product safety. Our Astragalus Extract is Non-Irradiated, Non-ETO, treated by Heat only.



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The newest third-party ETO test report is as bellow:



Page 1/1
AR-21-SU-086107-01

Analytical Report

Sample Code	502-2021-00101621	Report date	04-Oct-2021
Certificate No.	AR-21-SU-086107-01		



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Our reference:	502-2021-00101621/ AR-21-SU-086107-01
Client Sample Code:	KT-210915
Sample described as:	Astragalus Extract
Sample reception date:	29-Sep-2021
Analysis Starting Date:	29-Sep-2021
Analysis Ending Date:	03-Oct-2021

	Results	Unit	LOQ	LOD
★ VV88G Ethylene oxide Method: Internal method (ESQ-TP-1047)				
Ethylene oxide (sum of ethylene oxide and 2-chloro-ethanol expressed as ethylene oxide)	<LOQ	mg/kg	0.01	

SIGNATURE

 Haijia Qin
 Authorized Signatory

EXPLANATORY NOTE
 LOQ: Limit of Quantification ▲ CNAS # DAKK5 DCMA
 < LOQ: Below Limit of Quantification ☆ means the test is subcontracted within Eurofins group
 NA means Not applicable # means the test is subcontracted outside Eurofins group
 Sum compounds results are calculated from the results of each quantified compound as set by regulation
 The uncertainty has not been taken into account for standards that already include measurement uncertainty or on explicit request of client.
 The sample description and information are provided by the Client. Eurofins is not responsible for verifying the accuracy, relevancy, adequacy and/or completeness of the information provided by the Client.
 The analytical result herein is applicable for the sample(s) tested only.
 This analytical report shall not be excerpted or modified without prior written approval from Eurofins. The report shall be utilized in full.
 The result(s) is(are) only for internal use by the client and not for publicly available as evidence. Without the written permission of Eurofins, any party is prohibited from using the test results and the report for publicity or promotions or marketing.
 The Eurofins General Terms and Conditions apply to this analytical report.
 For and on behalf of Eurofins Technology Service (Suzhou) Co., Ltd

END OF REPORT

References:

1. Parisi AN, Young WE. Sterilization with ethylene oxide and other gases. In: Block SS, ed. Disinfection, sterilization, and



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preservation. Philadelphia: Lea & Febiger, 1991:580-95.

2. Occupational Safety and Health Administration. Ethylene Oxide: OSHA Fact Sheet: Occupational Safety and Health Administration, 2002

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