

United States Food and Drug Administration

Center for Drug Evaluation and Research

10903 New Hampshire Ave, Silver Spring, MD 20993, United States of America

CDERExportCertificateProgram@fda.hhs.gov - Telephone (301) 796-4950

Certificate of a Pharmaceutical Product - Active Pharmaceutical Ingredient (API)

Certificate Number: MA2T-TP62

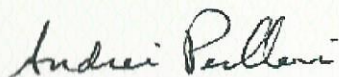
Certificate Issue Date: September 22, 2017

Certificate Expiration Date: September 21, 2019

Importing Country: GERMANY

Exporting Country: UNITED STATES of AMERICA

1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: ZINC OXIDE
1.1	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): See Attachments
1.2	Is this product licensed to be placed on the market for use in the exporting country? No
1.3	Is this product actually on the market in the exporting country? Yes
2.B.1	Applicant for certificate name & address: Zinc Oxide LLC, 600 Printwood Drive, Dickson, TN 37055 United States of America
2.B.2	Status of Applicant: Manufacturer
2.B.2.1	Manufacturer name & address: Zinc Oxide LLC, 600 Printwood Drive, Dickson, TN 37055 United States of America
2.B.3	Why is marketing authorization lacking? Not Applicable
2.B.4	Remarks: The firm proposes to export the active pharmaceutical ingredients (API) listed above, which when properly labeled with statement "Caution: For further manufacturing, processing or repacking", may be freely marketed in the United States of America at this time.
3.	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? Yes
3.1	Periodicity of routine inspections (years): Pursuant to section 510(h)(3) of the Federal Food, Drug & Cosmetic Act, Inspections will occur in accordance with a risk-based schedule
3.2	Has the manufacture of this type of dosage form been inspected? Yes
3.3	Do the facilities and operations conform to GMPs as recommended by the WHO? (GMPs including 21 Code of Federal Regulations parts 210, 211, or ICH Q7A): Yes, at time of inspection, site complies with FDA cGMP
3.4	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product undertaken by another party? Yes



Andrei Perlloni, Branch Chief
Drug Import Export Compliance Branch
Division of Imports, Exports & Recalls
Office of Drug Security, Integrity & Response

