

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by *Andrei Perlloni*

3. acting in the capacity of *Branch Chief, Office of Drug Security, Integrity & Response*

4. bears the seal/stamp of *U.S. Department of Health and Human Services*

Certified

5. at Washington, D.C.

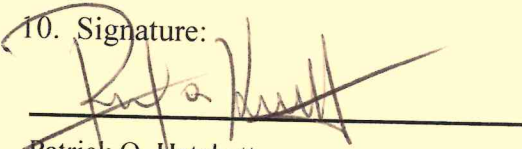
6. the *eighteenth* of December, 2018

7. by *Assistant Authentication Officer, United States Department of State*

8. No. *19011645-1*

9. Seal/Stamp:

10. Signature:


Patrick O. Hatchett

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 Expiration Date: November 20, 2020

Certificate Issue Date: November 21, 2018

Exporting Country: UNITED STATES of AMERICA

Certificate Number: BECF-A7E5

Importing Country: CHILE

1. Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **THIOGUANINE**

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: **AMPAC Fine Chemicals, Po Box 1718, Rancho Cordova, CA 95741 United States of America**

2.B.2 Status of Applicant: **Manufacturer**

2.B.2.1 Manufacturer name & address: **AMPAC Fine Chemicals, Po Box 1718, Rancho Cordova, CA 95741 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 repackaging", 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(b)(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 Petlloni

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



conforms to the format recommended by the World Health Organization format revised October 1, 1997. Website: www.who.int

THIOGUANINE

2-AMINO-1,7-DIHYDRO-6H-PURINE-6-THIONE

CAS #: 154-42-7

NDC: 50683-0356-1

Chemical Formula: $C_5H_5N_5$

DANGER!
TOXIC TO
AQUATIC
LIFE



CAUTION

Potent pharmaceutical agent. Toxic by ingestion. May produce mutagenic effects in human cells. May cause cancer. May produce adverse effects on the development of human offspring. Possible effects of overexposure in the workplace include: bone marrow toxicity; temporary decrease in platelet count; temporary decrease in white blood cell count; diarrhea; vomiting; nausea. Exposure might occur via inhalation; ingestion; skin; eyes. Dangerous for the environment. Very toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

PRECAUTIONARY STATEMENTS

P101: If Medical advice is needed, have product container or label at hand. **P103:** Read label before use. **P301+P310:** IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician. **P403+P233:** Store in a well-ventilated place. Keep container tightly closed.

HAZARD STATEMENTS

H301: Toxic if swallowed. **H312:** Harmful in contact with skin. **H317:** May cause an allergic skin reaction. **H332:** Harmful if inhaled. **H335:** May cause respiratory irritation. **H340:** May cause genetic defects. **H350:** May cause cancer.

EMERGENCY RESPONSE

Wear full protective clothing and Self Contained Breathing Apparatus (SCBA).

IN CASE OF FIRE

No special requirements needed. Water is recommended for fires involving packaging.

IN CASE OF SPILLS

Contain spills and control runoff. Keep material from being discharged to air, soil and waterways. Do not allow material to enter surface drainage system, sewers and poorly ventilated areas. Collect and place all material in an appropriately labeled hazardous waste container. After all solid or absorbent has been collected, the area should be vacuumed with HEPA filter-equipped apparatus. Dispose of in accordance with all applicable federal, state and local regulations.

FIRST AID PROCEDURES

Flush with water for 15 minutes. Seek immediate medical attention. If wearing appropriate PPE, move victim to fresh air in a safe area. Seek immediate medical attention. Attempt to induce vomiting. Wash the mouth out with water. If victim is fully conscious, give small sips of water to drink. Seek immediate medical attention.

This product until Safety Data Sheet M16173 has been read and

Product Code XXXXXXXX
Purchase Order # XXXXXXXX

Lot Number YY-356-XXX

Gross Wt.: xx.xx kg

Tare Wt.: xx.xx kg

Net Wt.: xx.xx kg

Date of Manufacture DD Month YYYY

Re-test Date DD Month YYYY

Container x of y

CAUTION: For manufacturing, processing or repacking

CAUTION: Federal Law prohibits dispensing without prescription

COUNTRY OF ORIGIN

United States of America

SHIPPING CLASSIFICATION

US DOT IATA Environmentally hazardous substance, solid, N.O.S. (THIOGUANINE). Hazard Class 9, PG III, UN 3077

STORAGE REQUIREMENTS

Store in tightly sealed containers at < 30°C protected from direct sunlight and moisture



Highway 50 & Hazel Avenue
Rancho Cordova, CA 95670

Emergency Telephone Number: 1 (800) 424-9300