

## 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, Drug Imports and Exports Compliance Branch

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

### Certified

5. at Washington, D.C.

6. the seventeenth of December, 2020

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

8. No. 21006332-1

9. Seal/Stamp:

10. Signature:

Chana M Turner



# 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: **EEU6-PE9M**

Certificate Issue Date: September 15, 2020

Certificate Expiration Date: September 14, 2022

Exporting Country: UNITED STATES of AMERICA

Importing Country:	<b>CHILE</b>
1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: <b>MELPHALAN</b>
1.1	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): <b>See Attachments</b>
1.2	Is this product licensed to be placed on the market for use in the exporting country? <b>No</b>
1.3	Is this product actually on the market in the exporting country? <b>Yes</b>
2.B.1	Applicant for certificate name & address: <b>AMPAC Fine Chemicals, Po Box 1718, Rancho Cordova, CA 95741 United States of America</b>
2.B.2	Status of Applicant: <b>Manufacturer</b>
2.B.2.1	Manufacturer name & address: <b>AMPAC Fine Chemicals, Hwy 50 and Hazel Avenue, Rancho Cordova, CA 95670 United States of America</b>
2.B.3	Why is marketing authorization lacking? <b>Not Applicable</b>
2.B.4	Remarks: <b>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.</b>
3.	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? <b>Yes</b>
3.1	Periodicity of routine inspections (years): <b>Pursuant to section 510(b)(3) of the Federal Food, Drug &amp; Cosmetic Act, Inspections will occur in accordance with a risk-based schedule</b>
3.2	Has the manufacture of this type of dosage form been inspected? <b>Yes</b>
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): <b>Yes, at time of inspection, site complies with FDA cGMP</b>
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? <b>Yes</b>

*Andrei Perlloni*

Andrei Perlloni, Branch Chief  
Drug Import Export Compliance Branch  
Division of Global Drug Distribution and Policy  
Office of Drug Security, Integrity & Response





**Melphalan, Milled**

4-[Bis-(2-chloroethyl)amino]-L-phenylalanine

CAS NO: 148-82-3

NDC: 50683-0385-1

Chemical Formula:  $C_{13}H_{18}Cl_2N_2O_2$ **DANGER!****HIGHLY TOXIC! CARCINOGENIC!**

Harmful or fatal if swallowed. May cause irritation to the eyes. Material is harmful by inhalation and will blister and destroy the skin. This product is a cytotoxic agent, a known carcinogen, mutagen, and possible human teratogen. Wear chemical goggles, full air suit, PVC or rubber gloves, and boots when handling. **WARNING:** This product contains a chemical known to the state of California to cause cancer and reproductive/developmental effects.

**HAZARD STATEMENTS**

**H333:** May be harmful if inhaled. **H335:** May cause respiratory irritation. **H360:** May cause genetic defects. **H370:** May cause cancer. **H380:** May damage fertility or the unborn child. **H301+H311+H331:** Toxic if swallowed, in contact with skin or if inhaled. **H315+H320:** Causes skin and eye irritation.

**PRECAUTIONARY STATEMENTS**

**P101:** If medical advice is needed, have product container or label at hand. **P103:** Read label before use. **P403+P233:** Store in a well-ventilated place. Keep container tightly closed.

**EMERGENCY RESPONSE**

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

**IN CASE OF FIRE**

Use dry chemical, foam, carbon dioxide, or water to extinguish flames. Control run-off. Avoid release to environment.

**IN CASE OF SPILLS**

Shovel into clean, dry waste containers. Dispose in accordance with all applicable federal, state, and local regulations.

**EMERGENCY AND FIRST AID PROCEDURES**

**EYES and SKIN:** Flush with water for 15 minutes. Get medical attention.

**INHALATION:** Remove victim to fresh air. Get medical attention.

**INGESTION:** DO NOT induce vomiting. Get medical attention.

**IMPORTANT!**

**Do not use this product until AFC Safety Data Sheet M16406 has been read and understood.**

Product Code: xxxxxxxxxx  
Purchase Order #: xxxxxxxxxx  
Lot Number: yy-385-xxx  
Gross Weight: x.xx kg  
Tare Weight: x.xx kg  
Net Weight: x.xx kg  
Travel Sample: x.x g

Date of Manufacture: DD MMM YYYY

Retest Date: DD MMM YYYY

Container: x of y

\*Included in net weight

CAUTION: For manufacturing, processing or repackaging

**SHIPPING CLASSIFICATION**

Hazard Class 6.1, POI, UN 2811 (RQ = 1.0 lb)

**STORAGE REQUIREMENTS**

Protect from light and moisture. Store in tightly closed containers in a clean, dry, well-ventilated area away from sources of ignition at a temperature of  $5 \pm 3^\circ\text{C}$ .



Hwy 50 and Hazel Ave  
Rancho Cordova, CA 95670  
Emergency Telephone Number  
+1(800) 424-9300

Control #: QAL-LB-0385 rev 5