

# DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

ATLAS CHEMICAL INDUSTRIES, INC.

## Notice of Withdrawal of Petition for Food Additives

Pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(b), 72 Stat. 1786; 21 U.S.C. 348(b)), the following notice is issued:

In accordance with § 121.52 *Withdrawal of petitions without prejudice* of the procedural food additive regulations (21 CFR 121.52), Atlas Chemical Industries, Inc., Wilmington, Del. 19899, has withdrawn its petition (FAP 8B2248), notice of which was published in the FEDERAL REGISTER of January 26, 1968 (33 F.R. 1026), proposing an amendment to § 121.2576 *Cross-linked polyester resins* to provide for the safe use of vinylcyclohexene dioxide as an optional component in cross-linked polyester resins intended for food-contact use.

Dated: September 17, 1968.

J. K. KIRK,  
Associate Commissioner  
for Compliance.

[F.R. Doc. 68-11699; Filed, Sept. 25, 1968;  
8:49 a.m.]

## GEIGY CHEMICAL CORP.

### Notice of Amended Filing of Petition Regarding Pesticides

Notice was given in the FEDERAL REGISTER of August 5, 1967 (32 F.R. 11389), that a petition (PP 7F0620) had been filed by the Geigy Chemical Corp., Ardsley, N.Y. 10502, proposing the establishment of tolerances for residues of the herbicide atrazine (2-chloro-4-ethylamino-6-isopropylamino-s-triazine) in or on the raw agricultural commodities: Perennial rye grass at 15 parts per million; pineapple (forage and fodder) at 10 parts per million; wheat (straw, forage, and hay) at 5 parts per million; and macadamia nuts, pineapple (fruit), sugarcane (cane, forage, and fodder), and wheat (grain) at 0.25 part per million.

Pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 408(d)(1), 68 Stat. 512; 21 U.S.C. 346a(d)(1)) and § 120.9 of the pesticide procedural regulations (21 CFR 120.9), notice is given that said petition has been amended by proposing additional tolerances for residues of atrazine in or on meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep at 0.1 part per million; and in milk at 0.05 part per million.

Dated: September 17, 1968.

J. K. KIRK,  
Associate Commissioner  
for Compliance.

[F.R. Doc. 68-11700; Filed, Sept. 25, 1968;  
8:49 a.m.]

## INTERNATIONAL MINERALS & CHEMICAL CORP.

### Notice of Filing of Petition Regarding Pesticide Chemicals

Pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 408(d)(1), 68 Stat. 512; 21 U.S.C. 346a(d)(1)), notice is given that a petition (PP 9F0751) has been filed by Markel and Hill, Munsey Building, Washington, D.C. 20004, on behalf of International Minerals & Chemical Corp., Skokie, Ill., proposing the establishment of an exemption from the requirement of a tolerance (21 CFR 120.1011) for residues of an insecticide containing viable spores of the micro-organism *Bacillus thuringiensis* Berliner in or on the raw agricultural commodities citrus, cucumbers, eggplants, okra, and peppers.

The analytical method proposed in the petition for determining residues of viable spores of *Bacillus thuringiensis* Berliner is a spore-count assay that consists of a standard plate-count procedure using a heat-treated suspension (60° C. for 60 minutes) of the material to be tested.

Dated: September 17, 1968.

J. K. KIRK,  
Associate Commissioner  
for Compliance.

[F.R. Doc. 68-11701; Filed, Sept. 25, 1968;  
8:49 a.m.]

## THOMPSON-HAYWARD CHEMICAL CO.

### Notice of Amended Filing of Petition Regarding Pesticides

Notice was given in the FEDERAL REGISTER of March 2, 1968 (33 F.R. 4116), that a petition (PP 8F0700) had been filed by the Thompson-Hayward Chemical Co., Post Office Box 2383, Kansas City, Mo. 66110, proposing the establishment of a tolerance for negligible residues of the fungicide triphenyltin hydroxide in or on the raw agricultural commodity peanuts at 0.05 part per million.

Pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 408(d)(1), 68 Stat. 512; 21 U.S.C. 346a(d)(1)) and § 120.9 of the pesticide procedural regulations (21 CFR 120.9), notice is given that said petition has been amended by proposing additional tolerances for negligible residues of triphenyltin hydroxide in or on meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep at 0.05 part per million.

Dated: September 17, 1968.

J. K. KIRK,  
Associate Commissioner  
for Compliance.

[F.R. Doc. 68-11702; Filed, Sept. 25, 1968;  
8:49 a.m.]

## VIOMYCIN SULFATE FOR INTRAMUSCULAR INJECTION

### Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports from the National Academy of Sciences—National Research Council, Drug Efficacy Study Group, on the following viomycin sulfate preparations for intramuscular use:

1. Vinactane Sulfate; 1 gram and 5 grams of viomycin (present as the sulfate) per vial; marketed by CIBA Pharmaceutical Co., 556 Morris Avenue, Summit, N.J. 07901.

2. Viocin Sulfate; 1 gram and 5 grams of viomycin (present as the sulfate) per vial; marketed by Charles Pfizer & Co., Inc., 235 East 42d Street, New York, N.Y. 10017.

3. Viomycin Sulfate; equivalent to 1 gram and 5 grams of viomycin per vial; marketed by Parke, Davis & Co., Joseph Campau at the River, Detroit, Mich. 48232.

The Food and Drug Administration concurs in the conclusions of the Academy that this drug is bacteriostatic against *Mycobacterium tuberculosis* and, when given with one or more other effective antituberculous agents, is suitable for treatment of active adult tuberculosis after failure of treatment with primary drugs.

Preparations containing this drug are subject to the antibiotic certification procedures pursuant to section 507 of the Federal Food, Drug, and Cosmetic Act. Batches of the drug for which certification is requested should be labeled in accord with the labeling information in this announcement. All suppliers are requested to submit, within 60 days from the date of publication of this announcement, supplements to their antibiotic form 5 or 6 applications to provide for revised labeling. Those parts of the labeling indicated below should be substantially as follows:

#### ACTION

Bacteriostasis against *Mycobacterium tuberculosis*.

#### INDICATIONS

Failure after adequate treatment with primary drugs (i.e. isoniazid, streptomycin, aminosalicylic acid) in any form of active adult tuberculosis. Viomycin should be given with one or more other effective antituberculous agents.

#### CONTRAINDICATION

Known hypersensitivity to viomycin.

#### WARNING

Viomycin should be used only when close observation of the patient is possible and when laboratory facilities are available.

Viomycin should be discontinued if hypersensitivity develops, as manifested by fever or rash.

Progressive renal insufficiency may require discontinuation of therapy.

Vertigo, tinnitus, or hearing loss appearing with viomycin therapy indicates eighth nerve damage which may require discontinuance of therapy.

**USE IN CHILDREN:** Safe use of this drug in children has not been established. Because of its potential toxicity, the use of viomycin in children should be avoided unless crucial to therapy.

#### PRECAUTIONS

Pretreatment examinations should include in vitro susceptibility tests of recent cultures of *M. tuberculosis* from the patient, as measured against viomycin and other antituberculous drugs.

Periodic determinations of renal function prior to and every 1 to 2 weeks during therapy (include serum Na, K, Cl, Ca, P, and Co<sub>2</sub>) as well as tests of vestibular and audiometric function for evidence of eighth cranial nerve damage should be performed.

#### ADVERSE REACTIONS

Toxic manifestations involve the following:  
1. Labyrinth: Vertigo; tinnitus (low pitch); and hearing loss.

2. Kidney: Nitrogen retention; decreased blood bicarbonate; decreased creatinine clearance; hematuria; proteinuria; cylindruria; and renal loss of K, Ca, and Cl (as also reflected in ECG changes), with resultant lowering of serum values.

Hypersensitivity reactions, including rash, eosinophilia, drug fever, and laryngeal edema.

#### DOSAGE AND ADMINISTRATION

Viomycin sulfate is to be administered by the intramuscular route only. Usual dosage of viomycin (calculated as the base) is 2.0 grams, given in divided doses at 12-hour intervals twice a week. The total duration of treatment with viomycin may be limited by toxicity, drug resistance, or relapse.

Viomycin should be administered in combination with one or more antituberculous drugs to which the patient's organisms have been shown to be susceptible.

The firms listed above have been mailed a copy of the NAS-NRC report together with a copy of the labeling conditions contained in this announcement. Any manufacturer, packer, or distributor of a drug of composition and labeling similar to the drug listed in this announcement or any other interested person may obtain a copy of the NAS-NRC report by writing to the Food and Drug Administration, Press Relations Office, 200 C Street SW., Washington, D.C. 20204.

Any interested person may submit written comments regarding this announcement within 30 days after its publication in the FEDERAL REGISTER. Comments should be addressed to the Special Assistant for Drug Efficacy Study Implementation, Bureau of Medicine, Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204.

This notice is issued pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 507, 52 Stat. 1050-51, as amended, 59 Stat. 463, as amended; 21 U.S.C. 352, 357) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: September 19, 1968.

HERBERT L. LEY, JR.,  
Commissioner of Food and Drugs.

[F.R. Doc. 68-11703; Filed, Sept. 25, 1968; 8:49 a.m.]

## DEPARTMENT OF TRANSPORTATION

### Coast Guard

[CGFR 68-108]

### PORTION OF DELAWARE RIVER, CHESTER, PA.

#### Closure to Navigation During Launching of "S.S. American Leader"

By virtue of the authority vested in me as Commandant, U.S. Coast Guard, by 49 CFR 1.4 (32 F.R. 5606) and Executive Order 10173 as amended by Executive Orders 10277, 10352, and 11249, I hereby affirm for publication in the FEDERAL REGISTER the order of J. J. McClelland, Captain, U.S. Coast Guard, Acting Commander, 3d Coast Guard District, who has exercised authority as District Commander, such order reading as follows:

#### PORTION OF DELAWARE RIVER, CHESTER, PA.

Under the authority of Title II of the Espionage Act of June 15, 1917, 40 Stat. 220, 50 U.S.C. 191 and Executive Order 10173 as amended, I declare that from 5 p.m., e.d.t., on Thursday, September 26, 1968, until completion of the launching at 7 p.m., e.d.t., Thursday, September 26, 1968, the following area is a security zone and I order that it be closed to any person or vessel due to the launching of hull No. 643, the *S.S. American Leader*:

The waters of the Delaware River, Chester, Pa., within the coordinates of latitude 39°50'55" N., longitude 75°20'48" W., at the shoreline of Chester, Pa., thence southeasterly to latitude 39°50'34" N., longitude 75°20'33" W., thence northeasterly to latitude 39°50'45" N., longitude 75°19'29" W., thence north to latitude 39°51'22" N., longitude 75°19'32" W.

No person or vessel may remain in or enter this security zone.

The Captain of the Port, Philadelphia, Pa., shall enforce this order.

The Captain of the Port may be assisted by employees and facilities of any State or political subdivision thereof or any Federal agency.

For violation of this order Title II of the Espionage Act of June 15, 1917 (40 Stat. 220 as amended, 50 U.S.C. 192), provides:

"If any owner, agent, master, officer, or person in charge, or any member of the crew of any such vessel fails to comply with any regulation or rule issued or order given under the provisions of this chapter, or obstructs or interferes with the exercise of any power conferred by this chapter, the vessel, together with her tackle, apparel, furniture, and equipment, shall be subject to seizure and forfeiture to the United States in the same manner as merchandise is forfeited for violation of the Customs Revenue Laws; and the person guilty of such failure, obstruction, or interference shall be punished by imprisonment for not more than 10 years and may, in the discretion of the court, be fined not more than \$10,000.

"If any other person knowingly fails to comply with any regulation or rule issued or order given under the provisions of this chapter, knowingly obstructs or interferes with the exercise of any power conferred by this chapter, he shall be punished by imprison-

ment for not more than 10 years and may, at the discretion of the court, be fined not more than \$10,000."

Dated: September 20, 1968.

F. E. TRIMBLE,  
Vice Admiral, U.S. Coast Guard,  
Acting Commandant.

[F.R. Doc. 68-11671; Filed, Sept. 25, 1968; 8:46 a.m.]

## CIVIL AERONAUTICS BOARD

[Docket No. 19170]

### AEROLINEAS EL SALVADOR, S.A.

#### Notice of Hearing

In the matter of the application of Aerolinas El Salvador, S.A., for the renewal of its foreign air carrier permit, authorizing the foreign air transportation of persons, property, and mail between a point or points in El Salvador and the terminal point, Miami, Fla.

Notice is hereby given, pursuant to the provisions of the Federal Aviation Act of 1958, as amended, that a hearing in the above-entitled proceeding is assigned to be held on October 2, 1968, at 10 a.m., e.d.s.t., in Room 911, Universal Building, 1825 Connecticut Avenue NW., Washington, D.C., before the undersigned Examiner.

Dated at Washington, D.C., September 20, 1968.

[SEAL] LESLIE G. DONAHUE,  
Hearing Examiner.

[F.R. Doc. 68-11685; Filed, Sept. 25, 1968; 8:47 a.m.]

[Docket No. 20263; Order 68-9-97]

### AIR CARRIER DISCUSSIONS

#### Order Regarding Common Fare Arrangement With Stopover Privileges in Conjunction With Service to Hawaii

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 20th day of September 1968.

By tariff filings initially marked to become effective September 16, 18, and 22, 1968, Pan American World Airways, Inc., jointly with American Airlines, Inc., and Trans World Airlines, Inc., Northwest Airlines, Inc., and United Air Lines, Inc., respectively, proposed round-trip economy class group inclusive tour-basing fares between selected Mainland points, on the one hand, and Honolulu and Hilo, Hawaii, on the other. In addition, Pan American proposed for October 5, 1968, effectiveness a tariff which would meet the Northwest proposal from the Pacific northwest. A complaint and a letter of protest, were filed against the joint proposal of Pan American, American, and Trans World Airlines, Inc., and complaints have also been lodged against the United pro-