U.S. Customs and Border Protection

Importing Chemicals Into the U.S.

10th DEA Chemical Industry Conference
September 17-18, 2008
Our Mission

We are the guardians of our Nation’s borders.
We are America’s frontline.
We safeguard the American homeland at and beyond our borders.
We protect the American public against terrorists and the instruments of terror.
We steadfastly enforce the laws of the United States while fostering our nation’s economic security through lawful international trade and travel.
We serve the American public with vigilance, integrity and professionalism.
CBP secures America’s borders to protect the American people and our economy.
It is a challenging task.

- 1,900 miles of border with Mexico
- 5,000 miles of border with Canada
- 326 “ports of entry”—official entry or crossing points
- 144 CBP Border Patrol stations with 345 permanent checkpoints
CBP’s strategy is layered and comprehensive.

Ensure border security against terrorists and other criminals, while facilitating legitimate trade and travel.

On a typical day, CBP:
- Processes 1.13 million incoming travelers,
- Processes 70,200 containers
- Apprehended nearly 2,402 people between ports for illegal entry and executes 70 criminal arrests at ports of entry
- Seizes 7,388 pounds of narcotics
- Seizes 4,296 prohibited agricultural items, including 164 plant pests at ports of entry
- Processes $88.8 million in duties and fees
We secure more than 300 ports of entry...

- **Inspecting cargo**: Layered, defense-in-depth strategy includes CSI, C-TPAT, 24-Hour Rule, Advance Notification, ATS, ATDI, and sophisticated detection and risk management systems.

- **Welcoming legitimate travelers, legal immigrants, and temporary residents**: US-VISIT, WHTI, SEVIS, NEXUS, SENTRI, IAFIS, machine-readable passport, preclearance.

- **Examining agricultural imports**: Protecting America’s agriculture, the environment, and the food supply from pests, diseases, and agroterrorism.
New technologies provide critical help...

- National Targeting Center
- Non-intrusive inspection systems: X-ray and gamma imaging, rail gamma imaging, radiation portal monitors, radiation detection pagers
- Sensors, video surveillance cameras, infrared devices and radiation detection devices to detect illegal border activity
- Unmanned aerial vehicles
…and so do time-tested assets.

Deploy daily:

- 1,173 canine enforcement teams
- 10,029 automobiles
- 267 aircraft
- 175 watercraft
- 188 equestrian patrols
CBP is the frontline agency of the Department of Homeland Security—charged with securing and managing our nation’s borders. We succeed by working as a team...

- 18,400 CBP officers
- 15,000 CBP Border Patrol agents
- 2,200 agriculture specialists
- 760 CBP Air & Marine Interdiction Agents
...and work with many partners.

- **Foreign/private sector**—
  - CSI: Operational in 50 ports in 28 countries
  - C-TPAT: 6,124 industry members
    - FAST/SENTRI/NEXUS
    - International trade agreements
    - World Customs Organization

- **Public sector**—
  - Immigration and Customs Enforcement
  - Citizenship and Immigration Services
  - Department of State
  - Coast Guard
  - Federal Bureau of Investigation
  - Department of the Treasury
  - Department of Commerce
  - Department of Agriculture
  - Department of the Interior
  - State, local, and tribal law enforcement agencies
We are a world-class law enforcement agency, dedicated to excellence...

- **Training**: Anti-terrorism, firearms and tactical training, Leadership Center, Border Patrol Academy, CBP Academy

- **Technology**: Cutting-edge analysis supporting anti-terrorism, narcotics and trade enforcement, intellectual property rights, and WMD detection

- **Professionalism**: Core values, Pledge to Travelers, Customer Service Center
…so that we can better secure America.
Harmonized Tariff Schedule of the United States

- USITC.GOV
- “Harmonized” vs. TSUSA
- 21 Sections/96 Chapters in Int’l Edition
- U.S. adds Chapter 98 and Chapter 99
- Over 1200 Headings/5200 subheadings
HTSUS “Rules of the Game”

- General Rules of Interpretation
- General Notes: Include various trade program rules
- Section and Chapter Notes
- Explanatory Notes: Not dispositive yet persuasive
Questions to consider when classifying chemicals

- What chapter do I use?
  - First, is it a separate chemical element or chemically defined compound, or is it a mixture of compounds?
  - If a compound, is it organic or inorganic?
Classification Of Mixtures

Mixtures or other formulations of compounds not found in these chapters are classified in chapters 30-38, based on their principal use.
General Organization of Chemicals in the HTSUS

- SECTION VI: PRODUCTS OF THE CHEMICAL OR ALLIED INDUSTRIES
- Section Notes
  - Chapter 28 Inorganic chemicals; organic or inorganic compounds of precious metals, of rare-earth metals, of radioactive elements or of isotopes
  - Chapter 29 Organic chemicals
  - Chapter 30 Pharmaceutical products
  - Chapter 31 Fertilizers
  - Chapter 32 Tanning or dyeing extracts; dyes, pigments, paints, varnishes, putty and mastics
  - Chapter 33 Essential oils and resinoids; perfumery, cosmetic or toilet preparations
  - Chapter 34 Soap, organic surface-active agents, washing preparations, lubricating preparations, artificial waxes, prepared waxes, polishing or scouring preparations, candles and similar articles, modeling pastes, "dental waxes" and dental preparations with a basis of plaster
  - Chapter 35 Albuminoidal substances; modified starches; glues; enzymes
  - Chapter 36 Explosives; pyrotechnic products; matches; pyrophoric alloys; certain combustible preparations
  - Chapter 37 Photographic or cinematographic goods
  - Chapter 38 Miscellaneous chemical products
Special Invoice Requirements

19 CFR 141.89(a) requires additional information for certain classes of merchandise.

- **CHEMICALS**
  - CAS#
  - Use of the product

- **COLORS, DYES, STAINS AND RELATED PRODUCTS OF 3204**
  - Invoice name of the product
  - Trade name of the product
  - Color index name
  - Color index number
  - CAS#
  - Class of merchandise (type of dye such as acid, disperse, vat, basic, etc)
  - Material to which it is applied (textiles, plastics, etc.)
Confidential Information

- 19 CFR 103.12(d)

- Pursuant to 5 U.S.C. 552(b), the disclosure requirements of 5 U.S.C. 552(a) are **not** applicable to Customs and Border Protection records which relate to:

- **Privileged or confidential information.** Trade secrets and commercial or financial information obtained from any person which is privileged or confidential.
General Notes Specific to the Chemical Industries

13. Pharmaceutical products. Whenever a rate of duty of "Free" followed by the symbol "K" in parentheses appears in the "Special" subcolumn for a heading or subheading, any product (by whatever name known) classifiable in such provision which is the product of a country eligible for tariff treatment under column 1 shall be entered free of duty, provided that such product is included in the pharmaceutical appendix to the tariff schedule. Products in the pharmaceutical appendix include the salts, esters and hydrates of the International Non-proprietary Name (INN) products enumerated in table 1 of the appendix that contain in their names any of the prefixes or suffixes listed in table 2 of the appendix, provided that any such salt, ester or hydrate is classifiable in the same 6-digit tariff provision as the relevant product enumerated in table 1.

14. Intermediate chemicals for dyes. Whenever a rate of duty of "Free" followed by the symbol "L" in parentheses appears in the special subcolumn for a heading or subheading, any product classifiable in such provision which is the product of a country eligible for tariff treatment under column 1 shall be entered free of duty, provided that such product is listed in the intermediate chemicals for dyes appendix to the tariff schedule.
Anatomy of a HTSUS Classification

- Ten digit code: 3206.20.0010
- First six are international and are the same from country to country (HTS).
- Next two are U.S.-specific and differentiate duty rates (HTSUS).
- Last two are also U.S.-specific and are for trade statistic differentiations (HTSUS).
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Quantity</th>
<th>Tariff Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>3206.11.00 00</td>
<td>Containing 80 percent or more by weight of titanium dioxide calculated on the dry matter</td>
<td>kg 6% 1/</td>
<td>Free (A, AU, BH, CA, CL, E, IL, J, JO, MA, MX, P, SG) 30%</td>
</tr>
<tr>
<td>3206.19.00 00</td>
<td>Other</td>
<td>kg 6% 1/</td>
<td>Free (A, AU, BH, CA, CL, E, IL, J, JO, MA, MX, P, SG) 30%</td>
</tr>
<tr>
<td>3206.20.00 00</td>
<td>Pigments and preparations based on chromium compounds</td>
<td>3.7%</td>
<td>Free (A, AU, BH, CA, CL, E, IL, J, JO, MA, MX, P, SG) 25%</td>
</tr>
<tr>
<td>3206.41.00 00</td>
<td>Ultramarine and preparations based thereon</td>
<td>kg 1.5%</td>
<td>Free (A, AU, BH, CA, CL, E, IL, J, JO, MA, MX, P, SG) 7.5%</td>
</tr>
</tbody>
</table>

Other coloring matters; preparations as specified in note 3 to this chapter, other than those of heading 3203, 3204 or 3205; inorganic products of a kind used as luminophores, whether or not chemically defined.
Classification Toolkit

- Rulings Program: cbp.gov : Click Legal, Rulings, Requirements for Electronic Ruling Requests
- CROSS: cbp.gov: Click Legal, Click **CROSS: Customs Rulings Online Search System**
- USITC.Gov
Ms. Janice Lambertucci
Ren-Pharm International, Ltd.
350 Jericho Turnpike, Suite 204
Jericho, NY 11753-1317


Dear Ms. Lambertucci:

In your letter dated December 16, 2002, you requested a tariff classification ruling.

The first product, Mirtazapine, is indicated for the treatment of depression.

The second product, Mometasone Furoate, is a synthetic corticosteroid possessing anti-inflammatory properties. It is used to relieve the inflammatory and pruritic manifestations of corticosteroid-responsive skin diseases.

The third product, Nifedipine, is indicated for the treatment of angina.

The fourth product, Orphenadrine Citrate, is indicated for use as a skeletal muscle relaxant.

The fifth product, Oxandrolone, is a synthetic anabolic steroid. According to the monograph appearing in the 2002 Physicians’ Desk Reference®, Oxandrolone is the active ingredient in Oxandrin®, which “[i]s indicated as adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight, to offset the protein catabolism associated with prolonged administration of corticosteroids, and for the relief of the bone pain frequently accompanying osteoporosis.”

The applicable subheading for Mirtazapine, imported in bulk form, will be 2933.59.4600, Harmonized Tariff Schedule of the United States (HTS), which provides for “Heterocyclic compounds with nitrogen hetero-atom(s) only: Compounds containing a pyrimidine ring (whether or not hydrogenated) in the structure: Other: Drugs: Aromatic or modified aromatic: Antidepressants, tranquilizers and other psychotherapeutic agents.” Pursuant to General Note 13, HTS, the rate of duty will be free.

The applicable subheading for Mometasone Furoate, imported in bulk form, will be 2937.22.0000, HTS, which provides for “Halogenated derivatives of adrenal cortical hormones.” The rate of duty will be free.

The applicable subheading for Nifedipine, imported in bulk form, will be 2933.39.4100, HTS, which provides for “Heterocyclic compounds with nitrogen hetero-atom(s) only: Compounds containing an unfused pyridine ring (whether or not hydrogenated) in the structure: Other: Drugs: Other.” Pursuant to General Note 13, HTS, the rate of duty will be free.

The applicable subheading for Orphenadrine Citrate, imported in bulk form, will be 2922.19.0900, HTS, which provides for “Oxygen-function amino-compounds: Amino-alcohols, other than those containing more than one kind of oxygen function, their ethers and esters; salts thereof: Other: Aromatic: Drugs.” Pursuant to General Note 13, HTS, the rate of duty will be free.

The applicable subheading for Oxandrolone, imported in bulk form, will be 2937.29.9050, HTS, which provides for “Steroidal hormones, their derivatives and structural analogues: Other: Anabolic agents and anabolics.” The rate of duty will be free.

This merchandise may be subject to the requirements of the Federal Food, Drug, and Cosmetic Act, which is administered by the U.S. Food and Drug Administration. You may contact them at 5600 Fishers Lane, Rockville, Maryland 20857, telephone number 301-443-1444.

In addition, Oxandrolone may be subject to the requirements of the Controlled Substances Act and/or the Controlled Substances Import and Export Act, which are administered by the Drug Enforcement Administration (DEA). You may contact them at 1405 I Street N.W., Washington, D.C. 20460, telephone number 202-307-1000.

This ruling is being issued under the provisions of Part 177 of the Customs Regulations (19 C.F.R. 177).

A copy of the ruling or the control number indicated above should be provided with the entry documents filed at the time this merchandise is imported. If you have any questions regarding the ruling, contact National Import Specialist Harvey Kuperstein at 646-733-3033.

Sincerely,
Robert B. Swierupski
Director,
National Commodity
Specialist Division
Multiple Agencies

- DEA 236 : CONTROLLED SUBSTANCES IMPORT / EXPORT DECLARATION
- EPA Toxic Substance Control Act (TSCA)
- EPA Form 3540.1 Notice of Arrival of Pesticides and Devices
- NRC licenses
- FDA
Import Safety Initiative

- Presidential Executive Order 13439: Dated July 18, 2007
- Review and assess current procedures aimed at ensuring safety of imported products
- Identify means to promote steps by which producers and importers can enhance safety of imported products
- Survey practices of federal, state, and local agencies regarding the safety of imports to identify best practices
- Enhance coordination among agencies
President Initiative

- Approximately $2 trillion of imported products entered the U.S. last year and experts project this will triple by 2015.

- FY 2006, 825,000 importers brought shipments into the U.S. 45% (372,631) were one-time importers.

- Federal government cannot and should not attempt to physically inspect every product entering the U.S.

- Although it is not possible to eliminate all risk with imported products, being smarter requires us to find new ways to protect American consumers and continually improve the safety of our imports.
Strategic Framework

- Shift from reliance on at the border to interdict unsafe products, to a cost-effective, prevention-focused model that identifies and targets those critical points in the import life cycle where the risk of unsafe products is greatest and verifies the safety of products at those important phases.

- Risk-based, prevention-focused model to help ensure that safety is built into products before they reach our borders.
  - Prevention
  - Intervention
  - Response
Immediate Actions

• Improve collaboration and information sharing with the private sector to improve the safety of imports

• Interoperability Acceleration-Instruct Executive Agencies to Complete Their Identification of Technical, Business and Legal Requirements for Operating Within the ACE/ITDS D

• Global Collaboration—Instruct agencies to develop and increase international cooperation and collaboration

• Agreements with Foreign Governments
Intellectual Property Protection


• Focus the work of the interagency Strategy Targeting Organized Piracy (STOP) and the U.S. government-private sector Coalition against Counterfeiting and Piracy Initiative on import safety issues.

• Expand information-sharing about counterfeit and other goods that infringe IPR among relevant U.S. departments and agencies to identify and target products, manufacturers and distributors with potential safety violations.

• Encourage companies that have registered trademarks with the U.S. Patent and Trademark Office to record their registrations with CBP.
Intellectual Property Rights (IPR)

- CBP has established National Intellectual Property Rights Coordination Center.
- Federal agencies working together
- Stop flow of counterfeit goods
- Help ensure safety of consumers
- Dismantle organizations profiting from sale of fake goods
- Identify trends and smuggling techniques for counterfeit and piracy goods
- Pharmaceuticals comprised 6% of the top IPR commodities seized in FY2007 with a total domestic value of $11,137,578.
Confidentially report suspected trade violations to CBP - Include:
- Type of trade violation
- Description of what has occurred
- Products or goods involved
- Alleged violator’s name and/or company
- Other information on a voluntary basis

Not intended for assertions of security issues such as terrorist activity. Health and safety issues for immediate threats should be called to 1-800-BE ALERT.
Helpful Information

- [www.cbp.gov](http://www.cbp.gov)
- CROSS
- eAllegations
- Trade Outreach
- IPR
- Trade Programs
- Anti-Dumping/Countervailing Duties
- [www.usitc.gov](http://www.usitc.gov)
U.S. Customs and Border Protection