

Pipeline and Hazardous Materials Safety Administration 400 Seventh Street, S.W. Washington, D.C. 20590

APR 1 2 2005

DOT-E 12762 (SECOND REVISION)

EXPIRATION DATE: March 31, 2007

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: Wellstat Biologics Corporation Gaithersburg, Maryland

2. PURPOSE AND LIMITATION:

- a. This exemption authorizes the transportation in commerce of certain flammable and corrosive materials in UN certified combination packages, not subject to shipping paper requirements. This exemption provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein.
- b. The safety analyses performed in development of this exemption only considered the hazards and risks associated with transportation in commerce.
- 3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
- 4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR §§ 172.200-205 in that shipping papers are not required.
- 5. <u>BASIS</u>: This exemption is based on the application of Wellstat Biologics Corporation dated February 28, 2005, submitted in accordance with § 107.109.

6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identi- fication Number	Packing Group
Ethanol or Ethyl alcohol or Ethanol solutions or Ethyl alcohol solutions	3	UN1170	II
Hydrochloric acid	8	UN1789	II
Sodium hydroxide solution	8	UN1824	III

7. SAFETY CONTROL MEASURES:

a. PACKAGING - Prescribed packaging is a combination package certified as a minimum to UN4G/Y32/S with a single inner polyethylene bottle with a capacity of not more than 20 liters.

b. OPERATIONAL CONTROLS -

- (1) Shipments are only authorized between Wellstat Biologics Corporation facilities at 930 Clopper Road and 45 West Watkins Mill Road, both in Gaithersburg, MD.
- (2) Shipment must be made using a motor vehicle operated by Wellstat Biologics Corporation.
- (3) Loading, unloading, and operation of the vehicle must be performed by trained personnel from Wellstat Biologics Corporation.
- (4) Each shipment must contain less than 1,000 lbs of hazardous materials.
- 8. SPECIAL PROVISIONS: A current copy of this exemption must be maintained at each facility where the package is offered or reoffered for transportation.
- 9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle.

- 10. MODAL REQUIREMENTS: A current copy of this exemption must be carried aboard each motor vehicle used to transport packages covered by this exemption.
- 11. COMPLIANCE: Failure by a person to comply with any of the following may result in suspension or revocation of this exemption and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 et seq:
 - o All terms and conditions prescribed in this exemption and the Hazardous Materials Regulations, 49 CFR Parts 171-180.
 - o Persons operating under the terms of this exemption must comply with the security plan requirement in Subpart I of Part 172 of the HMR, when applicable.
 - o Registration required by § 107.601 et seq., when applicable.

Each "Hazmat employee", as defined in § 171.8, who performs a function subject to this exemption must receive training on the requirements and conditions of this exemption in addition to the training required by §§ 172.700 through 172.704.

No person may use or apply this exemption, including display of its number, when this exemption has expired or is otherwise no longer in effect.

12. REPORTING REQUIREMENTS: Shipments or operations conducted under this exemption are subject to the Hazardous Materials Incident Reporting requirements specified in 49 CFR §§ 171.15 - Immediate notice of certain hazardous materials incidents, and 171.16 - Detailed hazardous materials incident reports. In addition, the grantee(s) of this exemption must notify the Associate Administrator for Hazardous Materials Safety -- OHMEA, in writing, of any incident involving a package, shipment or operation conducted under terms of this exemption.

Issued in Washington, D.C.:

Robert A. McGuire

Associate Administrator for Hazardous Materials Safety

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(DATE)

Continuation of DOT-E 12762 (2nd Rev.)

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration, Department of Transportation, Washington, D.C. 20590. Attention: DHM-31.

Copies of this exemption may be obtained by accessing the Hazardous Materials Safety Homepage at http://hazmat.dot.gov/exemptions Photo reproductions and legible reductions of this exemption are permitted. Any alteration of this exemption is prohibited.

PO: DBurger/alb