



U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, D.C. 20590

DEC 08 2015

Mr. Juan Miró
Project Manager, Engineering Department
Mallinckrodt Pharmaceuticals, formally Ikaria, Inc.
1060 Allendale Dr.
Port Allen, LA 70767

Reference No. 15-0102

Dear Mr. Miró:

This is response to your May 22, 2015 e-mail requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to filling Department of Transportation (DOT) specification cylinders. In your e-mail, you ask whether it is permissible to overfill a cylinder by 350 psia during the filling process to compensate for losing 350 psia when detaching the cylinder from the gas transfer system. The final pressure after the cylinder is ejected from the filling nozzle is below the marked service pressure.

The filling of the cylinder must comply with the applicable requirements in Part 173 Subpart G of the HMR. This subpart does not address the variation in pressure during the filling process. Section 173.301a(c) states that when offered for transportation, the pressure in a cylinder at 21 °C (70 °F) must not exceed the service pressure for which the cylinder is marked or designated, except as provided in § 173.302a(b) of the HMR. Except as otherwise provided in § 173.301a(d), the pressure in a cylinder may not exceed 5/4 times the service pressure at 55 °C (131 °F) when the cylinder is offered for transportation. Therefore, your operating procedures must ensure that these requirements are met when the cylinder is offered for transportation.

I hope this satisfies your request.

Sincerely,

T. Glenn Foster
Chief, Regulatory Review and Reinvention Branch
Standards and Rulemaking Division

Lehman
§ 193.304
Cylinders
15-0102

Dodd, Alice (PHMSA)

From: Geller, Shelby CTR (PHMSA).
Sent: Friday, May 22, 2015 11:52 AM
To: Hazmat Interps
Subject: FW: Interpretation Solicitation - Gas Transfill Process of DOT 3AL 3000 cylinder

Dear Shante and Alice,

Attached is a request for a formal letter of interpretation. I spoke with Mr. Miro about his request.

Thanks,
Shelby

From: Juan Miro [<mailto:Juan.Miro@ikaria.com>]
Sent: Friday, May 22, 2015 11:47 AM
To: PHMSA HM InfoCenter
Subject: RE: Interpretation Solicitation - Gas Transfill Process of DOT 3AL 3000 cylinder

Greetings,

To clarify my questions:

1. Does the DOT regulation allows overfilling of a cylinder @ 70F during the filling process to compensate for pressure loss during detachment of the cylinder from the filling manifold?
 - a. Filling Setpoint 3350 psia @ 70F.
 - b. Final Pressure of the cylinder after detachment from the filling manifold - 3000 psia @ 70F or below.
 - c. Cylinder type DOT 3AL 3000.

Hope this clarifies my request.

Thanks

Régards,

Juan Miró | Project Manager | Engineering Department
Mallinckrodt Pharmaceuticals, formerly Ikaria, Inc.
1060 Allendale Dr Port Allen, LA 70767
T 225-376-4373 | M 225-335-0817 | F 225-376-4493
<http://www2.mallinckrodt.com/ikaria/>

From: Juan Miro
Sent: Thursday, May 21, 2015 6:32 PM
To: 'phmsa.hm-infocenter@dot.gov'
Subject: RE: Interpretation Solicitation - Gas Transfill Process of DOT 3AL 3000 cylinder

Greetings,

Following up on the request below. Can you please inform what are the next steps discuss and obtain the interpretation?

Thank You

Regards,

Juan Miró | Project Manager | Engineering Department
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From: Juan Miro
Sent: Wednesday, May 06, 2015 2:48 PM
To: 'phmsa.hm-infocenter@dot.gov'
Subject: Interpretation Solicitation - Gas Transfill Process of DOT 3AL 3000 cylinder

Greetings,

My name is Juan Miró and I am the lead engineer of a medical gas manufacturing facility. I am soliciting an interpretation of DOT regulation regarding the process I am about to describe:

1. Container Closure:
 - a. DOT 3AL 3000 cylinder with water volume of 0.074L
 - b. Aluminum Schrader type spring loaded valve.
2. Gas
 - a. 1.14% (11400 ppm) Nitric Oxide balance Nitrogen
3. Process Steps:
 - a. Attach the container to gas transfer system
 - b. Evacuate the container to 30mTorr
 - c. Pressurize the container to 3350 psia @ 70F (cylinder spends less than 1 minute pressurized to this setpoint before losing pressure during the detachment process).
 - d. Detach the container from gas transfer system (pressure loss of 350 psia)
 - e. Final container pressure before 3000 psia @ 70F

The process described pressurizes the cylinder to 3350 psia @ 70F (3750 psia @ 70F is 5/4 of service pressure). Upon reaching 3350 psia the cylinder is ejected from the filling nozzle losing 350 psia in the ejection process. The final pressure of the cylinder is at 3000 psia or below. After these cylinder are filled the contents are analyzed providing a final pressure before transport of 2750 psia.

Does the process as described complies with DOT regulation? I have assessed the regulation and there is mention of heated compression but nothing is mentioned about compensating for sudden pressure loss at the end of the filling process.

Regards,

Juan Miró | Project Manager | Engineering Department
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