

SAFETY & TECHNOLOGY ORGANIZER

AUGUST 2017

ENCLOSED

Safety Topic: Carbon Dioxide Asphyxiation *Please contact Mike Dodd, GAWDA DOT, Security, OSHA & EPA Consultant for more information.*

Traffic Bulletin: Marking and Identification *Please contact Mike Dodd for more information.*

Medical, Food/Beverage and Specialty Gases Bulletin

- 1. What is the status of Draft Guidance for Medical Gases?
- 2. GAWDA Professional Compliance Seminar Audit Survival
- 3. Medical Gas Roundtable (08/25/2017) CGMP Practical validation for the cylinder plant
- 4. Webinars: Specialty Gas Fuel/Oxidizer Mixture Safe Practices; Food Gas Roundtable Part 117 Subpart C - Corrective actions and corrections, Verification, Validation
- 5. Micro Audit Suggestions

Please contact Tom Badstubner, GAWDA FDA Food, Medical and Specialty Gases Consultant, for more information.

GAWDA is pleased to distribute this information to: Distributor and Supplier Key Contacts and all Compliance Manual Owners. Please carefully review this mailing and be sure the information is passed to the appropriate person within your organization. Timely Safety data is a benefit of Membership in GAWDA.



SAFETY TOPIC



You can suffer an accidental death by asphyxiation from carbon dioxide (CO2). Customer employees, supplier employees, and drivers that work in or around CO2 need to know and understand its properties and recognize potential asphyxiation situations. In addition to the facts presented here, you should also review the content of your CO2 Material Safety Data Sheet (MSDS) with your employees.

CO2 Need to Know Facts

- It is a colorless, odorless gas and about 1.5 times as heavy as air. Since it is denser than air, high concentrations can occur in open pits and other areas below grade.
- It is an asphyxiant and displaces oxygen, which can cause death. At concentrations of 10 percent and above, it can result in unconsciousness in 1 minute or less.
- It can cause asphyxiation when leaks or discharges occur in enclosed areas, poor or unventilated work areas, or below grade locations that are not confined spaces.
- It can result in impairment in performance during prolonged exposure of 3 percent.
- It can increase the heart rate and blood pressure and can cause headaches, dizziness, sweating, rapid breathing, shortness of breath, dizziness, mental depression, visual disturbance, or shaking depending on the length of exposure and the strength of the concentration.

Other Facts About CO2

- It is relatively nonreactive and nontoxic.
- It will not burn or support combustion.
- It is normally present in the atmosphere at about 0.035 percent by volume.
- It can cause freeze burns or tissue damage upon contact with dry ice or compressed CO2.

SAFETY TOPIC

Driver delivery personnel must also be trained regarding the properties and hazards associated with CO2. In addition, these are some of the situations that the supplier sales person, driver and customer should be looking for at the customer location.

- Basement container installations should be avoided if at all possible.
- Container installations that are in confined, low or restricted space should have appropriate warning signs and floor-mounted positive ventilation systems to prevent both asphyxiation and pressure buildup.
- If concentrations of CO2 in the atmosphere are possible, a CO2 detector with an alarm system should be in place.
- The outlet from the pressure relief device must be piped outdoors for indoors, restricted, confined or limited space installations.
- Any type of built in discharge should be piped outdoors.
- All fill connections should be piped so the connections are made outdoors.
- Suggested wording for warning sign is:

CAUTION CARBON DIOXIDE GAS Ventilate before entering A high CO2 gas concentration may occur in this area and may cause asphyxiation.

Additional Information

OSHA issued an alert on the dangers of carbon dioxide deliveries in 1996. The subject of that alert still has merit today.

http://www.osha.gov/dts/hib/hib_data/hib19960605.html

If you ship and deliver carbon dioxide in tankers or micro bulk units, you should make sure you are following the requirements set out in the latest copies of the CGA pamphlets G-6, G-6.1, G-6.2, G-6.3, G-6.4, G-6.5 & G-6.6, which can be obtained at <u>www.cganet.com</u>. There is also a CGA Safety Bulletin SB-29, Injury and Loss Prevention Resulting from Carbon Dioxide Delivery to Small Customer Sites, which outlines the precautions when filling carbon dioxide containers indoors at customer sites. It is recommended you obtain a copy for review with your workforce. There are other CGA publications that you may find helpful in addition to those listed above.

As always, if there are questions or items that I can help you with, please don't hesitate to contact me.

Michael Dodd

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Traffic Bulletin

August 2017

Marking and Identification

"What information do I need to put on the side of my vehicle?" is a common question I receive. The follow-up questions are "What size and color should the markings be and where on the vehicle am I allowed to put the information?"

What are the regulations?

390.21 Marking of CMVs

All vehicles defined as commercial motor vehicles according to §390.5 and operating in interstate commerce must display prescribed identification information.

- The legal name or a single trade name of the motor carrier operating the selfpropelled CMV, as listed on the motor carrier identification report (Form MCS– 150) and submitted in accordance with §390.19.
- The motor carrier identification number issued by the FMCSA, preceded by the letters "USDOT".

If the name of any person other than the operating carrier appears on the CMV, the name of the operating carrier must be preceded by the words "operated by." Other identifying information may be displayed on the vehicle if it is not inconsistent with the required information.

How do I display the Information?

The markings must:

- Appear on both sides of the self-propelled CMV;
- Be in letters that contrast sharply in color with the background on which the letters are placed;
- Be readily legible, during daylight hours, from a distance of 50 feet (15.24 meters) while the CMV is stationary; and
- Be kept and maintained in a manner that retains the required legibility.

The marking may be painted on the CMV or may consist of a removable device.



Rented Vehicles

If you use a rented vehicle, please read 390.21 for the specific requirements of marking the vehicle and the paperwork requirements of what should appear on the contractual agreement.

Interstate versus Intrastate

The above information applies if your vehicle is in interstate commerce. If your vehicle is only involved in intrastate commerce, then slightly different sets of rules apply depending on your state.

The major differences are that some states require a city and state added to the name and DOT number markings. There are also some states that issue and require state DOT numbers to be displayed on the vehicle. Some states even require the VIN number to be displayed on the sides of the vehicles. Please see your respective state regulations for the specifics or ask me and I can look them up for you.

Motor Carrier Identification Number

A motor carrier identification number is obtained by filing Form MCS–150, available without charge from any FMCSA motor carrier safety service center or division office.

If you are applying for a USDOT number for the first time, then be aware that it very likely will generate a visit / audit from DOT to make sure that you have all the required records and programs in place as a motor carrier.

If there are any questions regarding this Bulletin, please ask.

Michael Dodd

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Medical, Food/Beverage and Specialty Gases Bulletin

08/01/2017

What is the status of Draft Guidance for Medical Gases?

The FDA issued the latest Draft Guidance for Medical Gases in late July, 2017. We held a GAWDA Roundtable Webinar on July 11 to review the proposed changes and consider our comments. The CGA Medical Gas and Regulatory Policy Group is using our comments and the comments from the major gas companies to develop a formal response to the agency. We have compared the new Draft Guidance to prior agency thinking, present regulations and CGA industry positions.

GAWDA and CGA will submit our comments to the FDA by the end of August and seek to meet with the agency to discuss our postion and get clarification on several unusual and new agency positions.

We will keep you informed as this work continues. For now, please continue to follow longstanding guidance and industry positions. When/if the agency issues Final Guidance, we may need to adjust some of our practices.

GAWDA Professional Compliance Seminar – Audit Survival

Hold The Date (October 17-19, 2017)... GAWDA Professional Compliance Seminar at Weldcoa, Aurora, IL. This seminar focuses on surviving DOT/FDA audits and Food/Beverage Gas Compliance.

August Medical Gas Roundtable (08/25/2017) – CGMP – Practical validation for the cylinder plant

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In August we will be discussing practical process validation techniques for cylinder fill operations:

- sample systems
- check valves
- fill processes
- portable fill manifolds

This seminar focuses on ways to save money while improving compliance.

For your information, we are also conducting the following webinars in August:

- Specialty Gas Fuel/Oxidizer Mixture Safe Practices
- Food Gas Roundtable Part 117 Subpart C Corrective actions and corrections, Verification, Validation

These and other webinars are available as a streaming recording at a time convenient to you. If you are unable to view the webinar live, just let us know and we will send you the link to the recording. If you would like to receive invitations to the training webinars, just send an email to jodie@asteriskllc.com.

Medical, Food/Beverage and Specialty Gases Bulletin

Micro-audit

This section of the Medical Gas Bulletin lists small steps you can take each month to improve your medical gas management system. These steps are not designed to be a full audit, but rather small steps to sample your compliance.

For this month, simply do these items:

- 1. **Portable Oxygen Manifolds –** If you are using a portable oxygen manifold, be sure you have validated and documented the manifold.
- 2. Automatic, mechanical or electronic equipment Be sure all major equipment used to produce your medical gases are covered in a maintenance program. The equipment that needs calibration should be within the calibration date (gauges, thermometers, etc.).

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