

SAFETY & TECHNOLOGY ORGANIZER

JULY 2016

ENCLOSED

Safety Topic: Hazard Communication Program, Frequently Asked Questions (FAQs) Please contact Mike Dodd, GAWDA DOT, Security, OSHA & EPA Consultant for more information.

Traffic Bulletin: Shipping Papers – Frequent Citations

Please contact Mike Dodd for more information.

Medical Gas Bulletin:

- **1. FAQ**: How should I respond if a customer needs Genetically Modified Organisms (GMO) certification?
- 2. **Medical Gas Roundtable** CGMP (07/29/2016) CGMP Subpart F Production and Process Controls: SOPs, filling cylinders, equipment identification, reprocessing, etc.
- 4. **Webinars**: **Medical Device Gases** QSR Subparts K, L & M Handling, Storage, Distribution, Installation, Packaging and Labeling Control, Records. **Specialty Gas** Making Highly Reliable Gravimetric Mixtures. **Food Gas Roundtable** CGMP Training Part 117 Subpart C Recall Plan & Preventive Control Management Components and Monitoring The latest information about food gas regulations is reviewed; The sample Food Gas SOPs are available for downloading during the seminar.

5. Mirco Audit Suggestions

Please contact GAWDA Medical Gas Consultant, Tom Badstubner 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

Safety Meetings are important!

They: get your employees actively involved encourage safety awareness

help identify problems before they become accidents motivate employees to follow proper safety procedures

We are happy to provide you with a monthly topic for your agenda.

| ROUTE TO: | |
|-----------|--------------------|
| | General Manager |
| | Safety Coordinator |
| | Supervisor Dept |
| | Other |
| | Date of Meeting |
| | 57 |

Hazard Communication Program, Frequently Asked Questions (FAQs)

Can SDSs be stored on a computer to meet the accessibility requirements of HAZCOM?

If the employee's work area includes the area where the SDSs can be obtained, then maintaining SDSs on a computer would be in compliance. If the SDSs can be accessed only out of the employee's work area(s), then the employer would be out of compliance with paragraphs (g)(8) or (g)(9) [of the Hazard Communication Standard].

What are the container labeling requirements under HAZCOM?

Under Hazard Communication Standard, the manufacturer, importer, or distributor is required to label each container of hazardous chemicals. If the hazardous chemicals are transferred into unmarked containers, these containers must be labeled with the required information, unless the container into which the chemical is transferred is intended for the immediate use of the employee who performed the transfer.

When is the chemical manufacturer required to distribute SDSs?

Hazard information must be transmitted on Safety Data Sheets (SDSs) that must be distributed to the customer at the time of first shipment of the product. The Hazard Communication Standard also requires that SDSs be updated by the chemical manufacturer or importer within three months of learning of "new or significant information" regarding the chemical's hazard potential.

What is considered proper training under the HAZCOM standard?

Employees are to be trained at the time they are assigned to work with a hazardous chemical. The intent of this provision (1910.1200(h)) is to have information prior to exposure to prevent the occurrence of adverse health effects. This purpose cannot be met if training is delayed until a later date.

The training provisions of the Hazard Communication Standard are not satisfied solely by giving employee the data sheets to read. An employer's training program is to be a forum for explaining to employees not only the hazards of the chemicals in their work area, but also how to use the information generated in the hazard communication program. This can be accomplished in many ways (audiovisuals, classroom instruction, interactive video), and should include an opportunity for employees to ask questions to ensure that they understand the information presented to them.

Training need not be conducted on each specific chemical found in the workplace, but may be conducted by categories of hazard (e.g., carcinogens, sensitizers, acutely toxic agents) that are or may be encountered by an employee during the course of his duties.

Furthermore, the training must be comprehensible. If the employees receive job instructions in a language other than English, then the training and information to be conveyed under the Hazard Communication Standard will also need to be conducted in a foreign language.

SAFETY TOPIC

What are the requirements for refresher training or retraining a new hire?

Additional training is to be done whenever a new physical or health hazard is introduced into the work area, not a new chemical. For example, if a new solvent is brought into the workplace, and it has hazards similar to existing chemicals for which training has already been conducted, then no new training is required. As with initial training, and in keeping with the intent of the standard, the employer must make employees specifically aware which hazard category (i.e., corrosive, irritant, etc.) the solvent falls within. The substance-specific data sheet must still be available, and the product must be properly labeled. If the newly introduced solvent is a suspect carcinogen, and there has never been a carcinogenic hazard in the workplace before, then new training for carcinogenic hazards must be conducted for employees in those work areas where employees will be exposed.

Do you need to keep SDSs for commercial products such as "Windex" and "White-Out"?

OSHA does not require that SDSs be provided to purchasers of household consumer products when the products are used in the workplace in the same manner that a consumer would use them, i.e.; where the duration and frequency of use (and therefore exposure) is not greater than what the typical consumer would experience. This exemption in OSHA's regulation is based, however, not upon the chemical manufacturer's intended use of his product, but upon how it actually is used in the workplace. Employees who are required to work with hazardous chemicals in a manner that results in a duration and frequency of exposure greater than what a normal consumer would experience have a right to know about the properties of those hazardous chemicals.

What are the requirements and limits to using generic SDSs?

... [Regarding] the suitability of a generic safety data sheet (SDS). As you are probably aware, the requirements for SDSs are found in paragraph (g) of 29 CFR 1910.1200. SDSs must be developed for hazardous chemicals used in the workplace, and must list the hazardous chemicals that are found in a product in quantities of 1% or greater, or 0.1% or greater if the chemical is a carcinogen. The SDS does not have to list the amount that the hazardous chemical occurs in the product.

Therefore, a single SDS can be developed for the various combinations of ... [chemicals], as long as the hazards of the various... mixtures are the same. This "generic" SDS must meet all of the minimum requirements found in 29 CFR 1910.1200(g), including the name, address and telephone number of the responsible party preparing or distributing the SDS who can provide additional information.

The above information comes from the OSHA website found at this link: http://www.osha.gov/html/faq-hazcom.html

OSHA gives links to actual Letters of Interpretation and other references for each of the questions and explanations given 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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July 2016

Shipping Papers – Frequent Citations

Have you reviewed your shipping paper lately? Several things have changed in the past few years and many, if not most of you, have made these changes, but I still run across shipping papers that have some of the following major mistakes on them.

- In 2005, a change was made required certain gases to show the subsidiary hazard class. If the material (other than combustible liquids) has a subsidiary hazard class shown in column 6 of the hazardous materials table found in 172.101, then it must be entered in parenthesis immediately following the primary hazard class or division number on the shipping paper. For example, oxygen gas will be shown as: Oxygen, compressed, 2.2 (5.1), UN1072 or an authorized alternate is UN1072, Oxygen, compressed, 2.2 (5.1).
- As of Jan.1, 2008, six gas descriptions were removed from the hazardous materials table. The most common ones for our membership were the elimination of the rare gas descriptions.
- As of Jan. 1, 2013, you must show the identification number (UN number) in front of the shipping name and then hazard class.
- Another new item is that you must show your company name on the shipping paper. This is in addition to already showing the emergency response company and phone number that you are using.

The following items are the most common mistakes that DOT finds on shipping papers:

- Failing to prepare a shipping paper.
- Failing to properly identify hazardous entries on a shipping paper that also includes non-hazardous entries.
- Failing to include the identification number, proper shipping name, hazard class, and/or packing group.
- Listing an improper identification number, proper shipping name, hazard class, and/or packing group.
- Including unauthorized information inside the basic description.
- Listing information in the basic description out of sequence.
- Failing to properly identify reportable quantities (RQs).
- Failing to provide the total quantity shipped.





- Failing to show a proper package type / name.
- Failing to include technical name(s) when required.
- Failing to list applicable special permit number(s).
- Failing to include or sign the required shipper's certification.
- Failing to include a 24-hour emergency response number.
- Failing to staff the listed number.
- Listing a fraudulent 24-hour number.
- Listing a number which is not working or is incorrect.
- The required response information is not listed on, or provided with, the shipping paper.
- The response information provided is inappropriate for the material.

The penalties for these mistakes can run into the thousands of dollars. If you have not reviewed your shipping paper recently, you should. I would be happy to review your shipping paper for you. I can spot mistakes very quickly and explain how to make the needed corrections. Just email me your shipping paper and I'll be happy to look it over.

Feel free to contact me on any of these items if you have questions.

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07/01/2016

Frequently Asked Questions

Q – How should I respond if a customer needs Genetically Modified Organisms (GMO) certification?

A – The European Union and the state of Vermont have passed regulations about labeling of products with GMO's. This has caused some food companies to request assurance that food gases do not contain GMO's. Our food/beverage gases do not contain proteins or "organisms" but are actually molecular compounds (e.g. carbon dioxide) or elements (e.g. nitrogen). We would typically not have any GMO's in our food gases.

The Compressed Gas Association is developing a position statement regarding GMO's. The position statement is expected to be be released shortly. When the CGA position statement is released, we will make available sample GMO certificates, consistent with industry positions. In the meantime, if you need further information, just send a message to tom@asteriskllc.com.

July Medical Gas Roundtable (07/29/2016) – CGMP - Subpart F – Production and Process Controls

These GAWDA Medical Gas roundtables are excellent sources of CGMP training and the latest industry compliance news. In June we covered how to survive an FDA audit.

In July, we will cover Subpart F – Production and Process Controls --- SOPs, filling cylinders, equipment identification, reprocessing, etc.

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

- Medical Device Gases QSR Subparts K, L & M Handling, Storage, Distribution, Installation, Packaging and Labeling Control, Records
- Specialty Gas Making Highly Reliable Gravimetric Mixtures
- Food Gas Roundtable CGMP Training Part 117 Subpart C Recall Plan & Preventive Control Management Components and Monitoring
 - o The latest information about food gas regulations is reviewed -
 - o The sample Food Gas SOPs are available for downloading during the seminar.

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 tom@asteriskllc.com.



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. **Authorized Procedures –** Verify that your Quality Control Unit has authorized your SOPs in writing.
- 2. **Following SOPs –** Be sure that your cylinder filling personnel are strictly following the authorized procedures. This is easily accomplished by taking a copy of the cylinder fill procedure to the manifold and watching the operator fill the cylinders.

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