

HAZARD COMMUNICATION GUIDANCE FOR DIACETYL AND FOOD FLAVORINGS CONTAINING DIACETYL

This guidance is not a standard or regulation, and it creates no new legal obligations. It is advisory in nature, informational in content, and is intended to assist employers in providing a safe and healthful workplace. Pursuant to the Occupational Safety and Health Act, employers must comply with safety and health standards promulgated by OSHA or by a state with an OSHA-approved state plan. In addition, pursuant to Section 5(a)(1), the General Duty Clause of the Act, employers must provide their employees with a workplace free from recognized hazards likely to cause death or serious physical harm. Employers can be cited for violating the General Duty Clause if there is a recognized hazard and they do not take reasonable steps to prevent or abate the hazard. However, failure to implement any specific recommendations in this guidance is not, in itself, a violation of the General Duty Clause. Citations can only be based on standards, regulations, and the General Duty Clause.

Introduction

Diacetyl (also called butanedione or 2,3-butanedione, molecular formula $C_4H_6O_2$) is a natural byproduct of fermentation and is also synthesized by chemical manufacturers. Diacetyl gives butter and certain food flavorings a distinctive buttery flavor and aroma. Food flavorings containing diacetyl are used in microwave popcorn and other snack foods, pet foods, candies, baked goods, and other food products.

Significant new information regarding the health effects of diacetyl and food flavorings containing diacetyl (FFCD) affects the information that must be conveyed to employers and employees under the Occupational Safety and Health Administration's (OSHA) Hazard Communication standard (HCS)(29 CFR 1910.1200). A review of existing hazard information on this chemical reveals that current material safety data sheets (MSDS) and labels do not routinely include newer health effects information. Updating MSDSs and labels will provide employers and employees with the information they need to understand the hazards associated with diacetyl and FFCD as well as appropriate protective measures to be taken. Dissemination of this newly updated information is needed to reduce exposures to these chemicals, which have been associated with respiratory illness and injury. This document provides hazard communication guidance for those manufacturers, importers, and employers who manufacture, import, or use diacetyl and FFCD. Guidance is provided for conducting appropriate hazard determinations, instituting control measures, updating labeling information, and training. This document provides guidance for using new information in hazard determinations and identifies potential short-comings with existing information in MSDSs. The HCS must be consulted for additional details regarding the standard's requirements.

Summary of Available Information

A number of employees exposed to FFCD have developed serious respiratory illness presenting with persistent dry cough, wheezing, shortness of breath upon exertion, and fixed airways obstruction on spirometry. Several employees have been diagnosed with asthma or bronchiolitis obliterans. Bronchiolitis obliterans occurs when small airways become inflamed and scarred, resulting in the thickening and narrowing of the airways. The symptoms and airways obstruction range from mild to severe, and do not improve when the employee goes home or on vacation. Because bronchiolitis obliterans is a rare disease, some employees may have been potentially misdiagnosed with asthma, bronchitis, emphysema, and/or pneumonia. The loss of pulmonary function associated with severe bronchiolitis obliterans is permanent and some patients have been placed on lung transplant waiting lists.

The National Institute for Occupational Safety and Health (NIOSH) has, and continues to investigate, the occurrence of severe lung disease in employees at microwave popcorn packaging plants (NIOSH, 2003) and flavorings manufacturing facilities (Kanwal and Kullman, 2007). NIOSH reported that medical tests of employees at microwave popcorn plants showed fixed airways obstruction, some cases consistent with bronchiolitis obliterans, and other respiratory illnesses such as occupational asthma. NIOSH concluded that the lung diseases identified in these microwave popcorn plant employees were likely due to exposure to butter flavoring chemicals (NIOSH, 2003; Kanwal, et al., 2006). NIOSH also described cases of fixed airways obstruction, including three cases consistent with bronchiolitis obliterans, among employees producing butter and vanilla flavorings containing diacetyl at a flavorings manufacturing facility (Kanwal and Kullman, 2007). NIOSH concluded that, in this facility, “[i]t is highly likely that exposures to diacetyl contributed to the occurrence of severe fixed obstructive lung disease...”, but that the role of other flavoring chemicals was unknown (Kanwal and Kullman, 2007).

NIOSH also reported that employees at microwave popcorn plants and a flavorings manufacturing facility experienced eye, nasal, and/or upper respiratory irritation and/or burns (NIOSH, 2003; Kanwal and Kullman, 2007). In some cases, skin and eye burns have required medical treatment. For more information about specific NIOSH Health Hazard Evaluations (HHE) regarding these chemicals, see <http://www.cdc.gov/niosh/homepage.html>.

Recent studies have shown respiratory tract damage and death among rodents exposed to diacetyl and butter flavorings containing diacetyl. Hubbs and co-investigators demonstrated in a preliminary study that exposure of rats to 198.4 ppm of diacetyl for 6 hours caused necrosis of the nasal and tracheal epithelium (Hubbs, et al., 2004). In another preliminary study, exposure of mice to 200 and 400 ppm diacetyl via inhalation for 6 hours per day over 5 days caused death, acute necrotizing rhinitis, and erosive or necrotizing laryngitis (Morgan, 2006). This same study also showed exposure of mice to 200 and 400 milligrams per kilogram (mg/kg) diacetyl via oropharyngeal aspiration caused bronchiolar fibrosis and death. Recent inhalation studies have demonstrated that exposure of rats to butter flavoring vapors containing high concentrations of diacetyl (300 ppm) caused epithelial injury in the nasal passages and pulmonary airways (Hubbs, et al., 2002).

Guidance on Hazard Determination

Health Effects: Manufacturers and importers of hazardous chemicals must consider the available human and animal data when determining hazards and should convey that information on the MSDS (29 CFR 1910.1200(d)(2) and Appendix B of the HCS). Many current MSDSs do not reflect any new information regarding health effects and respiratory hazards associated with diacetyl or FFCD. The following provides guidance on additional information that must be included in the health effects section of MSDSs for these substances.

All chemical manufacturers and importers of diacetyl are required under the HCS to report on the label and MSDS any new significant information they become aware of regarding the hazards of a chemical (29 CFR 1910.1200(g)(5)). Many diacetyl MSDSs currently reflect skin, eye, and respiratory tract irritation hazards associated with diacetyl, but do not provide any new information regarding all potential respiratory hazards. In addition, many MSDSs do not provide any recommendations on appropriate control measures, such as personal protective equipment. For purposes of the MSDS, the updated health hazard information noted in the above studies must be reported in the health effects section, including any signs and symptoms of exposure and recommended protective measures (29 CFR 1910.1200(g)(2)(iv) & 1200(2)(viii)). Specifically, chemical manufacturers and importers must convey information that animals exposed to diacetyl experienced damage to the nose and upper airways, including severe damage to cells lining the respiratory tract.

Chemical manufacturers and importers of food flavorings containing one percent or more diacetyl must convey information in the health effects section of an FFCD MSDS regarding the human health effects; i.e., that NIOSH has reported that employees exposed to butter flavorings containing diacetyl are at risk of developing occupational lung diseases and that in one instance, similar illnesses have been found among employees producing butter and vanilla flavorings containing diacetyl. Finally, these MSDSs must convey that contact with liquid or vapors can cause irritation to the skin, eyes, nose, and throat.

Chemical manufacturers and importers of any food flavoring containing one percent or more diacetyl must convey in the health effects section of the FFCD MSDS the hazard information regarding diacetyl from the animal studies previously discussed. They must also consider other available health effects information for all components greater than one percent, convey that information on the FFCD MSDS, and include appropriate hazard warnings on the labels.

While the HCS does not require that mixtures be tested to determine health hazards, chemical manufacturers and importers of mixtures (such as FFCD) may choose to conduct such testing (29 CFR 1910.1200(d)(5)(i)). Where a mixture has not been tested as a whole, it is assumed to present the same health hazards as do components which comprise one percent or greater of the mixture (0.1 percent or greater for carcinogens) (29 CFR 1910.1200(d)(5)). Manufacturers of mixtures, such as FFCD, may rely on the upstream chemical manufacturers' hazard determination for constituent substances (29 CFR 1910.1200(d)(5)(ii)). Mixtures are also assumed to present the same health hazards as components present in quantities less than one

percent (less than 0.1 percent for carcinogens) if there is evidence that the component still poses a health risk to employees in those concentrations (29 CFR 1910.1200(d)(5)(iv)).

Physical Hazards: Manufacturers and importers of FFCD may use whatever scientifically valid data are available to evaluate the physical hazard potential of the mixture (29 CFR 1910.1200(d)(5)(iii)). For FFCD and diacetyl, the primary physical hazard of concern is expected to be flammability.

A flammable liquid is any liquid having a flashpoint below 100 degrees Fahrenheit as determined by the Tagliabue Closed Tester, Pensky-Martens Closed Tester, or Setaflash Closed Tester for liquids (29 CFR 1910.1200(c)).

Diacetyl has a flashpoint of 47 degrees Fahrenheit and is, therefore, a flammable liquid. Manufacturers, importers, and employers who manufacture, import, or use diacetyl must include this information on the MSDS. For FFCD, a determination must be made as to whether the mixture itself is flammable based on the flammability of its components or on a flammability test of the mixture.

Guidance on Control Measures

Engineering Controls: NIOSH has determined that effective controls for employers in microwave popcorn packaging plants using FFCD include isolation of mixing processes (i.e. enclosures) and use of local and general exhaust ventilation to reduce inhalation exposure to FFCD (NIOSH, 2003). Such control measures may be able to be applied to other worksites using diacetyl and FFCD in processes similar to those in microwave popcorn packaging plants.

Respiratory Protection: Because there is no established permissible exposure limit (PEL), NIOSH Recommended Exposure Limit (REL), or other recommended exposure limit for diacetyl or FFCD, determining appropriate respiratory protection will depend on the specific conditions under which these chemicals are used. Employers must consider the operations, environmental conditions, and other factors when selecting appropriate respirators (29 CFR 1910.134(d)). When an employer has completed a hazard evaluation and has determined that respiratory protection is required, a suitable respirator must be selected. Based on the NIOSH investigations of microwave popcorn plants, a NIOSH-certified air-purifying respirator equipped with organic vapor cartridges in combination with particulate filters would provide the minimum level of protection. Supplied air respirators can also be used in these facilities. Powered air-purifying respirators (PAPRs) (with organic vapor cartridges and particulate filters) are acceptable alternatives and may be easier for employees to wear in hot mixing rooms.

Personal Protective Equipment: Gloves and aprons made from butyl rubber, Teflon™, or Tychem™ are effective in reducing skin contact with ketones to prevent skin irritation. Since diacetyl is a ketone and certain FFCD may contain more than one ketone, it is reasonable to assume that these materials may provide some protection from exposure via skin contact to diacetyl and FFCD. Chemical-resistant gloves or sleeves, or other appropriate protection for exposed skin must be used when handling liquid, paste, or powdered flavoring ingredients that

could cause dermal injury (29 CFR 1910.138). Employers must also ensure that employees use chemical goggles or other appropriate eye protection when working with diacetyl and liquid FFCD when exposure to these chemicals is likely to cause injury to the eye (29 CFR 1910.133).

Chemical manufacturers and importers of diacetyl and FFCD must indicate any specific applicable precautions for safe handling on the MSDS (29 CFR 1910.1200(g)(2)(viii)). Chemical manufacturers and importers must also determine generally applicable control measures such as appropriate engineering controls, work practices, or personal protective equipment, and include that information on the MSDS (29 CFR 1910.1200(g)(2)(ix)). Such information, for example, would indicate that areas where diacetyl and FFCD are present must be adequately ventilated.

Guidance on Product Labels

Containers of food flavorings are subject to the labeling requirements of the HCS unless they are covered by the labeling provisions under the Federal Food, Drug, and Cosmetic Act or the Virus-Serum-Toxin Act of 1912 (29 CFR 1910.1200(b)(5)(iii)). It is expected that most workplace labels will not generally be subject to this exception.

The HCS requires that manufacturers and employers determine and provide appropriate hazard warning language for labels. Based on the hazard information described above, labels for containers of diacetyl must contain hazard warning statements similar to the following in order to meet the intent of the HCS (29 CFR 1910.1200(f)(1)):

Diacetyl

DANGER Can cause damage to respiratory tract and lungs if inhaled

Highly flammable

WARNING Can cause eye, skin, nose, and throat irritation

Responsible party name and contact information

Based on current information, labels for containers of food flavorings containing one percent or more diacetyl must contain hazard warning statements similar to the following in order to meet the intent of the HCS (29 CFR 1910.1200(f)(1)):

FFCD name

DANGER Can cause damage to respiratory tract and lungs if inhaled

WARNING Can cause eye, skin, nose, and throat irritation

Responsible party name and contact information

Guidance on Training and Information

The HCS requires employers to inform employees about the requirements of the standard, operations where hazardous chemicals are present, location of the written HCS program, location of MSDSs, and the location of the hazardous chemical inventory (29 CFR 1910.1200(h)(2)).

Employers are required to train employees in the methods used to detect the presence or release of a hazardous chemical, the physical and health hazards of the chemical, and control measures (including work practices, emergency procedures, and personal protective equipment) (29 CFR 1910.1200(h)(3)).

Updated MSDSs and labels provide necessary baseline information for employee training regarding physical and health hazards, personal protective equipment, and emergency procedures. Chemical manufacturers, importers, and employers who use diacetyl or FFCD must evaluate those operations and tasks where these chemicals are present and provide the required information and training to employees. Employers should determine whether additional training is required. New hazard information discussed in this guidance, such as occurrences of fixed airways obstructive disease in employees exposed to diacetyl and FFCD, may warrant additional training.

References

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Department of Labor. 29 CFR 1910.133, Eye and Face Protection.

Department of Labor. 29 CFR 1910.134, Respiratory Protection.

Department of Labor. 29 CFR 1910.138, Hand Protection.

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