

Chapter 8: Hazard Prevention and Control of Exposure to Diacetyl and 2,3-Pentanedione

8.3.7 Informing Workers about the Hazard

8.3.7.1 Safety and Health Programs

Employers should establish a comprehensive safety and health training program for all workers who are performing any activity, such as manufacturing, using, handling, or disposing of diacetyl or 2,3-pentanedione, that involves exposure to these compounds or mixtures that include these compounds. This program should include training on workplace hazards, monitoring of airborne diacetyl and 2,3-pentanedione levels, and medical surveillance of employees exposed to these compounds or mixtures that include these compounds. All containers of food flavorings fall under the labeling requirements of the OSHA hazard communication standard (HCS) unless they are covered under the Federal Food, Drug and Cosmetic Act or the Virus-Serum-Toxin Act of 1913 [29 CFR 1910.1200 (b)(5)].

Worker training should include information outlined in the OSHA HCS in the section titled “Employee Information and Training” [29 CFR 1910.1200 (h)(3)]. This includes information about diacetyl and 2,3-pentanedione and mixtures containing these compounds to which workers are exposed, explanation of safety data sheets and label elements, appropriate routine and emergency handling procedures, and recognition of the adverse health effects of exposure to these compounds, as well as other training requirements outlined in the OSHA HCS.

OSHA revised the HCS to align with the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS) in March 2012. This revision provides detailed criteria for hazard classification as well as new label elements (pictograms, signal words, hazard statements, and precautionary statements) and establishes a standardized safety data sheet (SDS) format. An SDS (formerly known as a material safety data sheet or MSDS) is a form that communicates the hazards of hazardous chemicals and mixtures and guidance for safe use. As of June 1, 2015, OSHA will require that SDSs adhere to a uniform format, and include 16 sections that require specific information for the chemical or mixture listed on the SDS. More information

1 on SDSs can be found on the OSHA HCS website
 2 [<https://www.osha.gov/dsg/hazcom/index.html>]. Employers should be aware of the changes,
 3 requirements, phase-in dates, and compliance effective dates of the revised HCS standard.
 4 OSHA has provided additional information on the phase-in requirements and dates for the
 5 transition to the revised HCS on their website [<http://www.osha.gov/dsg/hazcom/index.html>].

6 **8.3.7.2 GHS Classifications of Diacetyl and 2,3-Pentanedione**

7
 8 NIOSH has provided the following classification and labeling recommendations for diacetyl
 9 (Table 8-2 and 2,3-pentanedione (Table 8-3) according to the hazard classification and labeling
 10 elements outlined in the hazard communication standard [29 CFR 1910.1200]. These
 11 classifications are based on the data from worker investigations (Chapter 3) and from
 12 experimental toxicology studies (Chapter 4). OSHA has provided guidance on hazard
 13 communication for diacetyl and food flavorings that contain diacetyl [OSHA 2013] on the basis
 14 of the previous version of the HCS, but that guidance does not address some of the requirements
 15 in the revised HCS based on GHS.

16
 17 Table 8-2. Hazard classifications of diacetyl

Health hazards*				
GHS endpoint	Hazard category [reference]	Pictogram	Hazard phrase	Signal word†
Acute toxicity	Category 2, inhalation [Hubbs et al. 2008]		Fatal if inhaled	Danger
Serious eye damage/ eye irritation	Category 1, serious eye damage [Sugai et al. 1990]		Causes serious eye damage	Danger
Skin sensitization	Category 1B, skin sensitizer [Anderson et al. 2011]		May cause an allergic skin reaction	Warning
Specific target organ toxicity-single exposure	Category 1 [Hubbs et al. 2008]		Causes damage to the respiratory system if inhaled	Danger
Specific target organ toxicity-repeated exposure	Category 1 [Morgan et al. 2008; National Toxicology Program 2011]		Causes damage to respiratory system through prolonged or repeated exposure if inhaled	Danger

Table 8-2. Hazard classifications of diacetyl (continued)

Physical hazards*				
Flammable liquid	Category 2 [Illovo Sugar Limited 2009; Lide 2008; Sigma Aldrich 2010]		Highly flammable liquid and vapor	Danger

*Precautionary statements for the health and physical hazard classifications presented can be found in Appendix C of the hazard communication standard [29 CFR 1910.1200].

†Appendix C of the hazard communication standard [29 CFR 1910.1200] provides several precedence rules regarding the application of pictograms and signal words as well as rules for combining or omitting hazard and precautionary statements. These precedence rules save space on the label and improve readability.

Table 8-3. Hazard classifications of 2,3-pentanedione

Health hazards*				
GHS endpoint	Hazard category [reference]	Pictogram	Hazard phrase	Signal word
Acute toxicity	Category 2, inhalation [Hubbs et al. 2012; Morgan et al. 2012]		Fatal if inhaled	Danger
Skin sensitization	Category 1B, skin sensitizer [Anderson et al. 2011]		May cause an allergic skin reaction	Warning
Specific target organ toxicity-single exposure	Category 1 [Hubbs et al. 2012]		Causes damage to the respiratory system if inhaled	Danger
Specific target organ toxicity-repeated exposure	Category 1 [Morgan et al. 2012]		Causes damage to respiratory system through prolonged or repeated exposure if inhaled	Danger
Physical hazards				
Flammable liquid	Category 2 [Chem Service Inc. 1988; Merck Chemicals International 2010][	Highly flammable liquid and vapor	Danger

* Precautionary statements for the health and physical hazard classifications presented can be found in Appendix C of the hazard communication standard [29 CFR 1910.1200].

8.3.7.3 Classifying Mixtures Containing Diacetyl and 2,3-Pentanedione

The HCS indicates that mixtures that contain compounds that require classification and labeling can be evaluated under a set of bridging principles if no toxicological data are available for the mixture itself. These bridging principles can be applied when there is “sufficient data on both the individual ingredients and similarly tested mixtures to adequately characterize the hazards of the

1 mixture” [29 CFR 1910.1200.A.0.5]. If these bridging principles cannot be applied, the HCS
2 provides specific cut-off values/concentration limits that are specified for each health hazard
3 class and category. Most of these specific cut-off values/concentration limits are either $\geq 0.1\%$ or
4 $\geq 1\%$, under which mixtures containing classified compounds should be labeled accordingly.

5
6 However, a few endpoints have different specific cut-off value/concentration limits specified.
7 For most of the chemical hazards for which NIOSH made classifications (Tables 8-2 and 8-3),
8 the specific cut-off values/concentration limits specified by the HCS are $\geq 1\%$. Exceptions
9 include the hazard category for “serious eye damage/eye irritation” ($\geq 3\%$) and for “flammable
10 liquids,” for which the HCS does not have a cut-off value/concentration limit. If these mixtures
11 contain classified compounds below the specified HCS cut-off values/concentration limits,
12 classification and labeling of those mixtures are not usually required. However, the standard
13 indicates that “while the adopted cut-off values/concentration limits adequately identify the
14 hazard for most mixtures, there may be some that contain hazardous ingredients at lower
15 concentrations than the specified cut-off values/concentration limits that still pose an identifiable
16 hazard” [29 CFR 1910.1200.A.0.4.3.1]. As explained below, this is an important consideration
17 for mixtures containing diacetyl and 2,3-pentanedione.

18
19 Cal/OSHA provided industrial hygiene monitoring results from a Flavor Industry Safety and
20 Health Evaluation Program (FISHEP) evaluation in 2006 and 2007 at a food flavoring
21 manufacturer for the production of vanilla dry blend product [Cal/OSHA 2013]. In this
22 evaluation, task-based personal breathing zone sample concentrations of diacetyl collected over
23 19 minutes ranged from 3.5 to 5 ppm during dispensing of dry powder containing 0.14% diacetyl
24 by weight. If a TWA exposure was calculated over an 8-hour work shift, assuming no other
25 diacetyl exposure during the work shift, the 8-hour TWA exposure would have been 0.19 ppm.
26 Additionally, NIOSH has documented diacetyl exposures in investigations where employees
27 worked with flavoring mixtures with $< 1\%$ diacetyl by weight resulting in exposures over the
28 REL [NIOSH 2008a, b, 2009a, b]. One laboratory-based study also identified emissions of
29 diacetyl from natural butter and butter flavor powders, pastes, and liquid products in a laboratory
30 environment [Rigler and Longo 2010]. Determinations show that even in the butter flavoring
31 containing the lowest amount of diacetyl in the bulk flavoring (1.01% by weight), heating this

1 flavoring to 37.5°C released vapor concentrations of diacetyl as high as 13.67 ppm. This
2 suggests that even if diacetyl is present in bulk concentrations of <1%, vapor concentrations of
3 diacetyl could greatly exceed the NIOSH REL. NIOSH does not have data to confirm this same
4 relationship between concentrations in bulk mixture and air for 2,3-pentanedione. Although the
5 vapor pressure of 2,3-pentanedione (21.4 mm Hg at 20°C) is lower than diacetyl (52.2 mm Hg at
6 20°C) and will not volatilize as readily as diacetyl at room temperature, the initial boiling point
7 of 2,3-pentanedione (108°C) suggests that it is still a volatile organic compound [EPA 2013] that
8 can readily enter the vapor phase upon heating, leading to worker exposures.

9
10 The data presented in this criteria document strongly suggest that diacetyl and 2,3-pentanedione
11 are toxic to the respiratory system at very low vapor concentrations. For this reason, NIOSH
12 recommends that flavoring mixtures that contain diacetyl or 2,3-pentanedione at any
13 concentration that under the anticipated conditions of use could generate vapors exceeding the
14 NIOSH REL should carry the pictogram, hazard phrase, signal word, and precautionary
15 statements for the *specific target organ toxicity-single exposure* and *specific target organ*
16 *toxicity-repeated exposure* endpoints on labels and SDSs. If specific cut-off values can be
17 established otherwise, this recommendation does not need to be followed.

18
19 Regarding the other endpoints under which diacetyl and 2,3-pentanedione have been classified
20 by NIOSH (Tables 8-2 and 8-3), NIOSH does not have any data to suggest that mixtures
21 containing these compounds in concentrations less than the specific cutoff values/concentration
22 limits specified by the HCS are hazardous. This includes the *acute toxicity, skin*
23 *corrosion/irritation, serious eye damage/eye irritation, skin sensitization, and flammable liquid*
24 *endpoints* for diacetyl, and *acute toxicity and flammable liquid endpoints* for 2,3-pentanedione.
25 We recommend that manufacturers carefully evaluate whether mixtures containing these
26 compounds below the cut-off values/concentration limits specified in the HCS should be labeled.

27
28 The Flavor and Extract Manufacturers Association (FEMA) has recommended that several
29 flavoring substances, including diacetyl and 2,3-pentanedione, should include the following label
30 warning if they are present in compounded flavors (including liquid and dry or powdered
31 mixtures) in any concentration if they will be heated during processing [FEMA 2012]:

1
2 *WARNING – This flavor may pose an inhalation hazard if improperly handled. Please contact*
3 *your workplace safety officer before opening and handling, and read the MSDS. Handling of this*
4 *flavor that results in inhalation of fumes, especially if the flavor is heated, may cause severe*
5 *adverse health effects.*

6
7 FEMA has also recommended that this same warning should be used for containers of neat
8 substances such as diacetyl and 2,3-pentanedione as well as other “high priority” substances
9 listed in the FEMA guidance document. Additionally, FEMA has recommended that all
10 containers of compounded flavors (liquid and dry or powdered) or natural flavoring complexes
11 that contain diacetyl, 2,3-pentanedione or other high priority flavoring substances in
12 concentrations of >1.0% should be labeled with the above warning [FEMA 2012]. It is of note
13 that the use of the word “warning” in the FEMA text above conflicts with standardized GHS
14 terminology.

15
16 *8.3.7.4 Labeling and Posting*

17
18 To communicate hazard information effectively to workers, employers should:

- 19 • Post appropriate labeling on all flavoring product containers according to the HCS
20 requirements [29 CFR 1910.1200]. In this document, NIOSH is providing the
21 recommended label elements, including signal word, hazard statements, and
22 pictograms, that should be included for labeling of diacetyl and 2,3-pentanedione
23 on SDSs and labels for shipping containers [See Tables 8-2 and 8-3]. The
24 precautionary statements that are also required can be found in Appendix C to the
25 HCS [29 CFR 1910.1200]. NIOSH also recommends that mixtures containing
26 diacetyl or 2,3-pentanedione at any concentration that could generate vapors that
27 could exceed the NIOSH REL carry the pictogram, hazard phrase, and signal
28 word for the *specific target organ toxicity- single exposure* and *specific target*
29 *organ toxicity- repeated exposure* classifications until it can be demonstrated that
30 mixtures containing these compounds in concentrations less than the specific cut-
31 off values/concentration limits specified by HCS are not harmful.

- 1 • Place the following warning, as recommended by FEMA [FEMA 2012], on
2 containers of compounded flavors that contain diacetyl, 2,3-pentanedione, or
3 other flavoring substances identified by FEMA in any concentration if the flavors
4 are to be heated: *This flavor may pose an inhalation hazard if improperly*
5 *handled. Please contact your workplace safety officer before opening and*
6 *handling, and read the MSDS. Handling of this flavor that results in inhalation of*
7 *fumes, especially if the flavor is heated, may cause severe adverse health effects.*
8 Note: While NIOSH agrees with the content of the italicized text above, NIOSH
9 removed the word “warning” as stated in the original FEMA guidance. NIOSH
10 recommends that the word “warning” should not be included on hazard
11 statements containing diacetyl or 2,3-pentanedione, as this word has specific
12 meaning and conflicts with standardized HCS signal word terminology.
- 13 • Post warning labels and signs describing the health risks associated with flavoring
14 chemical exposures at entrances to work areas and inside work areas where
15 diacetyl, 2,3-pentanedione, or other flavoring chemicals are used.
- 16 • Post warning labels and signs describing any needs for PPE in the work area.
- 17 • Post the statement “Wear Respiratory Protection in this Area” if respiratory
18 protection is required.
- 19 • Print all labels and warning signs in English and in the predominant language of
20 workers who do not read English.
- 21 • Verbally inform workers about the hazards and instructions printed on the labels
22 and signs if they are unable to read them.
- 23 • Follow the requirements of the HCS for classifying and labeling diacetyl, 2,3-
24 pentanedione, and other flavoring chemicals. The OSHA website has additional
25 information on the hazard communication standard at
26 [\[http://www.osha.gov/dsg/hazcom/index.html\]](http://www.osha.gov/dsg/hazcom/index.html).

27 8.3.7.5 Training

28
29 Workers should receive training as mandated by the HCS [29 CFR 1910.1200]. As part of the
30 training, employers should also:

- 1 • Inform all potentially exposed workers, including temporary and contract
2 workers, about diacetyl or 2,3-pentanedione-associated health risks such as acute
3 toxicity, skin irritation and sensitization, eye irritation or damage, respiratory
4 disease, and flammability hazards.
- 5 • Train workers to report to management any eye or skin problems that may be
6 associated with exposure to flavoring chemicals and any persistent or worsening
7 respiratory symptoms such as cough, shortness of breath, or wheezing.
- 8 • Train workers to recognize hazardous situations.
- 9 • Inform workers about practices or operations that may generate airborne diacetyl
10 or 2,3-pentanedione concentrations above the REL (e.g., mixing).
- 11 • Establish procedures for reporting hazards and giving feedback about actions
12 taken to correct them.
- 13 • Train workers in the proper use and maintenance of implemented engineering
14 controls to protect them from hazardous exposures.
- 15 • Train workers in the proper use and maintenance of PPE.
- 16 • Inform workers about other flavoring chemicals that may pose occupational
17 exposure hazards.

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