

“Although Proposition 65 has benefited Californians, it has come at a cost for companies doing business in the state. They have incurred expenses to test products, develop alternatives to listed chemicals, reduce discharges, provide warnings, and otherwise comply with this law. *Recognizing that compliance with Proposition 65 comes at a price, OEHHA is working to make the law’s regulatory requirements as clear as possible and ensure that chemicals are listed in accordance with rigorous science in an open public process.*”

Office of Environmental Health Hazard Assessment, *Proposition 65 in Plain Language*,
<http://www.oehha.ca.gov/prop65/background/p65plain.html> (last visited Mar. 31, 2014)
(emphasis added)

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April 3, 2014

VIA EMAIL AND FIRST CLASS MAIL

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Re: APTCO, LLC's Comments in Opposition to Proposed Section 25904, Listings by Reference to the California Labor Code

Dear Dr. Alexeeff:

These comments are submitted on behalf of APTCO, LLC, a Delano-based company that manufactures grape boxes and wine "shippers" for California's table grape and wine producers. APTCO takes this opportunity to comment again on the Office of Environmental Health Hazard Assessment's (OEHHA) proposed Labor Code listing regulation.

I. INTRODUCTION

APTCO has already spent thousands of dollars to oppose the invalid provisions of OEHHA's last proposed Labor Code regulation. It is inexcusable and a violation of the due process rights of companies like APTCO that they should be required to spend substantial amounts of money continuing to oppose these periodic permutations of a Labor Code listing regulation. It is poor regulatory practice that OEHHA continues to spend the public's resources proposing a regulation that violates California law, ignores Proposition 65 case law and disregards the principles of fundamental fairness and due process.

Instead of eliminating each invalid provision of the original proposed Labor Code regulation after APTCO and other commentators extensively analyzed for OEHHA why the original version would have exceeded the scope of its well-defined statutory authority under Proposition 65, and instead of staying within the bounds of the statutory authority which Proposition 65 gives OEHHA and which the courts have established for OEHHA several times over the past 25 years, OEHHA continues to reinterpret the meaning of "within the scope of the federal Hazard Communication Standard" in an apparent effort to list chemicals under Proposition 65 from the National Toxicology Program's (NTP) Report on Carcinogens (RoC) without scientific review.

OEHHA now claims that “within the scope of the federal Hazard Communication Standard” (HCS) means it may list chemicals by reference to Safety Data Sheet (SDS) “information” rather than by reference to chemical “identifications” or “classifications.” Proposition 65, however, authorizes OEHHA to list only “substances *identified* by reference in Labor Code Section 6382(d)” (emphasis added).

The courts have held since 1989 that substances “identified” by reference in Labor Code Section 6382(d) refers only to those substances the federal Occupational Safety and Health Administration (OSHA) requires to be classified or “identified” as hazardous substances or carcinogens. E.g., Styrene Information and Research Center (SIRC) v. OEHHA, 214 Cal. App. 4th, 1082, 1089-90 (2012). The courts have never held that Labor Code Section 6382(d) refers to those substances for which OSHA requires certain “toxicological information” to be included on SDSs.

OEHHA claims that this proposed regulation “clarifies an existing process already used by OEHHA for listing and de-listing chemicals under Proposition 65,” misleading the public into believing that this Labor Code regulation is valid because it merely explains how OEHHA has always listed chemicals by reference to Labor Code Section 6382(d). In reality, OEHHA is attempting with this proposal to expand its listing authority with a novel method for listing chemicals under Proposition 65.

OEHHA does not tell the public that it has never listed chemicals from NTP and International Agency for Research on Cancer (IARC) listings based on SDS “information.” It does not tell the public that OSHA does not consider NTP and IARC “information” that may be in a SDS to constitute “identifications” of a chemical as a carcinogen for purposes of hazard communication in the workplace. OEHHA also does not tell the public that the courts have never ruled that Proposition 65 authorizes OEHHA to list chemicals by reference to SDS “information.”

OEHHA does not even state in proposed Subsection (a)(2) that it is proposing for the first time to find that chemicals are “known to the state to cause cancer” when they are not classified as carcinogens in the HCS. And the words “Safety Data Sheets” are not even mentioned in proposed Subsection (a)(2). This proposed regulation borders on being administrative sleight of hand.

Finally, not only has OEHHA disregarded the economic impact to the public of continuing for over a year to propose invalid interpretations of its Labor Code listing authority, and of proposing a Labor Code regulation three times in the past six years – each time with a different interpretation of its listing authority, but OEHHA claims in its Initial Statement of Reasons (ISOR) that it relied on an Economic Impact Analysis (EIA) to find that this proposed regulation will have no economic impact to the public. ISOR at 3. OEHHA’s EIA, however, does not contain any facts or data to support its finding of “no economic impact.” EIA at 9. It appears that OEHHA, again, did not perform an EIA. See EIA at 9.

II. DISCUSSION

A. PROPOSED SUBSECTION (a)(2) IS ENTIRELY OUTSIDE THE BOUNDS OF OEHHA'S STATUTORY AUTHORITY AND MUST BE WITHDRAWN OR REWRITTEN TO EXPLAIN THAT OEHHA MAY LIST ONLY FROM OSHA'S LIST OF CARCINOGENS IN SUBPART Z OF THE FEDERAL HAZARD COMMUNICATION STANDARD

Proposed Subsection (a)(2) provides:

(a) Pursuant to Section 25249.8(a), of the Act, a chemical shall be included on the list of chemicals known to the state to cause cancer or reproductive toxicity if it is a substance identified by reference in Labor Code Section 6382(b)(1) or by reference in Labor Code Section 6382(d) as causing cancer or reproductive toxicity.

....

(2) A Chemical shall be included on the list if it is within the scope of the Federal Hazard Communications Standard and is identified in the most recent version of Title 29 of the Code of Federal Regulations, part 1910.1200, adopted by the federal Occupational Safety and Health Administration, as causing cancer or reproductive toxicity based on sufficient animal or human evidence.

OEHHA explains in its ISOR (not in the proposed regulation itself) that this provision means it will list chemicals under Proposition 65 based on the SDS Rule located in Appendix D of the HCS. ISOR at 6-8.

HCS Appendix D provides:

A safety data sheet (SDS) shall include the information specified in Table D.1 under the section number and heading indicated for sections 1-11 and 16. If no relevant information is found for any given subheading within a section, the SDS shall clearly indicate that no applicable information is available. Sections 12-15 may be included in the SDS, but are not mandatory.

Table D.1—Minimum Information for an SDS	
Heading	Subheading
....	
2. Hazard(s) identification	(a)classification of the chemical in accordance with paragraph (d) of § 1910.1200;
11. Toxicological information	Description of the various toxicological (health) effects and the available data used to identify those effects, including: ... (e) Whether the hazardous chemical is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition), or by OSHA.

OEHHA explains what Subsection (a)(2) means in its ISOR:

Subsection (a)(2) of the proposed regulation describes the process by which OEHHA identifies chemicals or substances that are “within the scope” of the federal Hazard Communication Standard.

...

New Mandatory Appendix D of the 2012 version of the federal Hazard Communication Standard provides that a “safety data sheet (SDS) shall include the information specified in Table D.1...” (emphasis added). Item 11 of Table D.1 is entitled “Toxicological Information” and states that the SDS must include a description of the various toxicological (health) effects and the available data used to identify those effects, including:

...“(e) Whether the hazardous chemical is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or

has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition), or by OSHA”...

Because Mandatory Appendix D of the Hazard Communication Standard requires a safety data sheet to disclose that a workplace chemical is listed in the NTP Report on Carcinogens or has been found to be a potential carcinogen in the IARC Monographs, such chemicals clearly fall “within the scope” of the federal Hazard Communication Standard for purposes of Labor Code Section 6382(d), and therefore must be included on the Proposition 65 list.

ISOR at 6-7 (italics and underlining are OEHHA’s).

The analysis below will show that Proposition 65 permits OEHHA to list by reference to the HCS *only* those chemicals that: 1) have been *identified* or *classified*; 2) *in the HCS*; 3) *by OSHA*; and 4) *as carcinogens*. OSHA does not *identify* or *classify* chemicals as carcinogens in its SDS rule, nor has OSHA ever identified carcinogens in its SDS rule. Proposition 65 uses the term “identified”, and so the courts have always held that OEHHA’s authority extends only to those chemicals that have in fact been *classified* or *identified* as carcinogens. They have never held that OEHHA can list chemicals as “known to the state to cause cancer” based on toxicological *information*.

OEHHA’s provision in Subsection (a)(2) that “[a] Chemical shall be included on the list if it is . . . *identified* in the most recent version of Title 29 of the Code of Federal Regulations, part 1910.1200” (emphasis added) is consistent with Proposition 65 and the established case law. OEHHA, however, must rewrite the proposed rule to state clearly that that it will only list those substances that are in fact *identified* by OSHA as carcinogens in the HCS.

1. **The Courts have established for OEHHA what “within the scope of the federal Hazardous Communication Standard” means without reference to the SDS rule.**

OEHHA implies that its proposal to list by reference to SDSs is justified by describing the 2012 version of the SDS rule as “new” in its ISOR. See ISOR at 7. The 2012 version of this rule is not “new,” however. It existed in its present form in 1986, when Proposition 65 was enacted, except for a few minor, non-relevant amendments, such as to the formatting of SDSs. Compare HCS 1983 & HCS 1986, 29 C.F.R. § 1900.1200(g), with HCS 2012, 29 C.F.R. § 1900.1200(g) & Appendix D (1983 & 1986 versions are attached).

Most importantly for purposes of proposed Subsection (a)(2), the toxicological “information” subsection of the SDS rule, which OEHHA is now proposing to list from, also has not changed since 1986. See *id.* OSHA plainly explains this fact on its website: “Section 11. Toxicological Information. This section contains no new requirements other than format.”

<https://www.osha.gov/dsg/hazcom/side-by-side.html> (last visited Mar. 31, 2014). OSHA has

retained in the 2012 HCS the provision requiring a notation on SDSs of NTP and IARC information. It made that clear. OEHHA has ignored OSHA's clarity by claiming that the OSHA rule is "new" in order to justify a "new" interpretation of its listing authority.

OEHHA's new interpretation is not legally justified because OEHHA is only permitted to refer to mandatory chemical "identifications" or "classifications" in the HCS for Proposition 65 listings, as will be shown below. The rule addressing mandatory identifications or classifications is located in 29 C.F.R. § 1919.1200(d) and its corresponding Appendix A, not in the SDS rule, which is located in 29 C.F.R. § 1910.1200(g) and Appendix D. It is 29 C.F.R. § 1910.1200(d)(3) (formerly §§ (d)(3) and (d)(4)) and Appendix A § A.6.4.2, from which the substances "within the scope of the federal Hazard Communication Standard" can be found, as the California Courts of Appeal have explained over the years.

In 1989, 2011 and 2012, the Courts of Appeal interpreted for OEHHA what this phrase means. Each court held that it means that OEHHA may list only those substances that have been *identified* by OSHA as carcinogens or reproductive toxins in the HCS, and they all held that the way OSHA *identifies* chemicals as carcinogens or reproductive toxins in the HCS is by means of mandatory presumptions, which the courts described as OSHA's "floor lists." The floor lists contain the substances that OSHA mandates that all manufacturers must *classify* as carcinogens or reproductive toxins.¹

The Court of Appeal in AFL-CIO v. Deukmejian, 212 Cal. App. 3d 424, 435-38 (1989), addressed the Labor Code Listing Mechanism and explained what the Proposition 65 Labor Code listing mechanism's reference to Labor Code Section 6382(d) means. The Court examined the language in Proposition 65 and the intent expressed in Proposition 65's ballot initiative and found that listing by reference to the HCS means that the Proposition 65 list was meant to include substances which "are presumed conclusively by HCS to be carcinogens." Id. at 437. The Court explained that "the HCS defines as 'carcinogens' all substances listed by IARC in categories 1 and 2 as well as substances identified and listed by NTP as known or probable human carcinogens . . . and certain other substances listed by OSHA." Id.

The Deukmejian Court examined the HCS to determine OEHHA's listing authority. The HCS that the Court examined contained the same SDS rule as the current HCS, but the Court did not even mention that the SDS rule was relevant to the substances OEHHA is permitted to list under Proposition 65. This makes sense because OSHA requires "classifications" in the section of the HCS the Court analyzed, but OSHA requires only "information" in SDSs.

¹ Because OSHA eliminated the American Conference of Governmental Industrial Hygienists (ACGIH) "floor list" from the 2012 HCS, which OEHHA had been authorized to refer to for reproductive toxin Proposition 65 listings, OEHHA is no longer authorized to list reproductive toxins on Proposition 65 by reference to the HCS, as OEHHA acknowledges in its ISOR.

The Court of Appeal in Chamber of Comm. v. Brown, 196 Cal. App. 4th 233, 261 (2011), agreed with the Deukmejian Court's analysis. Likewise, the Court did not mention the SDS rule. It held that although "Labor Code Section 6382, subdivision (d), does not expressly refer to any listing source, . . . [this section's] explicit reference to 'substances within the scope of the federal [HCS]' . . . provides a clear roadmap to the listing sources it embraces." It explained that those sources were located in subparts (d)(3) and (d)(4) of the HCS, which were the provisions containing what the Court described as "floor lists." Id. The Court concluded: "In light of the established regulatory history, the reference in Section 25249.8, subdivision (a), to Labor Code Section 6382, subdivision (d), which, in turn, refers to any substance 'within the scope of the federal [HCS]' (Lab. Code, § 6382, subd. (d)), reflects an intent to encompass the 'floor lists'" Id. at 264. The sources listed in section (d)(4) were the NTP's RoC, the IARC Monographs and OSHA's list of hazardous substances in 29 C.F.R. section 1910, subpart Z. Id. at 261-62.

Finally, the Court of Appeal in SIRC v. OEHHA, 210 Cal. App. 4th 1082 (2012) agreed with the established holding that the Labor Code's reference to "substances within the scope of the HCS" was meant to encompass the "floor lists." Id. at 1089-90. The Court did not hold that this phrase was meant to encompass Mandatory Appendix D's required toxicological information. See id. It explained the basis of its holding: "The HCS 'was created in 1983' [citation omitted] Two provisions of the HCS require a manufacturer, importer or employer to treat a chemical as a hazardous substance if it is identified as such by certain sources One such provision is relevant to the present matter. Subpart (d)(4) identifies the following sources as establishing that a chemical is 'a carcinogen or potential carcinogen for hazard communication purposes: (i) National Toxicology Program (NTP), Annual Report on Carcinogens (latest edition); (ii) International Agency for Research on Cancer (IARC) Monographs (latest editions); or (iii) 29 C.F.R. part 1910, subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration.'" Id. at 1090 (italics and citations omitted).

In sum, the HCS rule requiring "classifications" or "identifications" is the only rule which relates to OEHHA's listing power. OSHA amended this relevant rule by eliminating two "floor lists"—the IARC's and the NTP's—but retained its own "floor list." OEHHA is not permitted to reinterpret its listing authority as a result of this amendment because the Courts' established holdings were clear and still apply: OEHHA can list from OSHA's "floor list" of carcinogens.

In analyzing the particular facts in Brown, the Court noted that although the specific language in Labor Code Section 6382(b)(1) or (d) has not changed since Proposition 65 was enacted, the lists of hazardous substances which are located within the HCS have changed throughout the years. The Court found also that Proposition 65 "anticipates change" because it mandates an annual revision of the Proposition 65 list, for example by listing or de-listing substances according to changes in the referenced lists. See Brown, 196 Cal. App. 4th at 258. The Court did not go on to find, however, that Proposition 65 authorizes OEHHA to change its own listing authority when OSHA's "floor lists" change. See id. See also, SIRC v. OEHHA at 1097.

The HCS's mandatory lists changed in 2012, but OEHHA's listing authority to list from OSHA's mandatory lists has not changed. The fact that OEHHA is permitted now to list from only one list does not mean that it can simply write a regulation that would expand its listing authority for the first time in 28 years to list by reference to a different, non-relevant rule in the HCS. And it does not mean that OEHHA can expand its listing authority for the first time in 28 years to refer to toxicological "information" in the HCS rather than actual carcinogen "identifications" or "classifications" in the HCS in order to list chemicals as "known" to cause cancer.²

OEHHA tells the public on its website that "[r]ecognizing that compliance with Proposition 65 comes at a price, OEHHA is working to make the law's regulatory requirements as clear as possible and ensure that chemicals are listed in accordance with rigorous science and in an open public process." OEHHA, Proposition 65 in Plain Language, <http://www.oehha.ca.gov/prop65/background/p65plain.html>. To remain true to this commitment OEHHA must withdraw its proposal to list chemicals by reference to SDS information. Listing in this manner is legally unjustified and would have the effect of allowing OEHHA to circumvent rigorous scientific review.

Importantly, the courts preclude administrative agencies from offering a new interpretation of their authority that rejects the interpretation which has been definitely adopted by a court as its own. E.g., Henning v. Industrial Welfare Commission, 46 Cal. 3d 1262, 1270 (1988) (noting also that an administrative agency cannot "change its mind" with a new construction). For that reason too, OEHHA cannot adopt Subsection (a)(2) as proposed.

2. OEHHA has concluded that the original ACGIH "floor list" is no longer a definitive source for identifying chemicals by reference to the HCS; likewise, the NTP and IARC lists are no longer definitive sources for identifying chemicals by reference to the HCS.

OEHHA explains in its ISOR that it can no longer list from the ACGIH list. ISOR, p. 7. This list was one of OSHA's floor lists—just as was the NTP's, the IARC's and OSHA's. For the same legal reasons that OEHHA can no longer list from the ACGIH list by reference to the HCS, OEHHA may no longer list from the NTP's and IARC's lists by reference to the HCS. It is confusing and unclear, and it is not supported by the law for OEHHA to propose a regulation allowing it to list from the NTP's and IARC's lists while recognizing that it can no longer list from the ACGIH's list. There is no principled or legal difference.

² Subsection D.1.3 of Appendix D requires that SDSs contain in Section 2 the "classification of the chemical in accordance with paragraph (d) of § 1910.1200." Under the HCS, chemicals that are not classified as carcinogens in the HCS in accordance with paragraph (d) of § 1910.1200 and its corresponding Appendix A, could nevertheless have corresponding SDSs that contain NTP and/or IARC information in Section 11 if those organizations have classified the chemicals as carcinogens or potential carcinogens.

3. **OEHHA’s emphasis on two words in Appendix D — “mandatory” and “shall” — to justify why it now proposes to list from SDS “information” is arbitrary and capricious.**

OEHHA highlights the words “mandatory” and “shall” from the SDS rule to justify its proposed new listing authority: “Safety Data Sheets (*Mandatory*) A safety data sheet *shall* include the information specified in Table D-1. . . .” 29 C.F.R. § 1910.1200, App. D (emphasis added).

The use of the words “mandatory,” “shall” and “require” in the SDS rule refers to what OSHA requires to be in the content and format of an SDS and is not relevant to the “mandatory” carcinogen lists the courts have established that OEHHA can list from, as can be seen from reading the SDS rule and from following the case law analysis above. As with OEHHA’s now withdrawn “Director’s List” proposal in the last version of this proposed regulation, it is arbitrary and capricious for OEHHA to propose and require the public to submit written comments objecting to a rule that would give OEHHA the authority to list under Proposition 65 based on several words that OEHHA has pulled completely out of context in order to expand its listing authority.

OEHHA ignores the Courts of Appeal’s established interpretation of its Labor Code listing authority and instead rests its listing authority solely on two words—“mandatory” and “require,” which it emphasizes out of context to the point of distortion.

OEHHA’s purported legal basis for proposed Subsection (a)(2) is the following: “chemicals clearly fall ‘within the scope of the federal Hazard Communication Standard’” because “Mandatory Appendix D of the Hazard Communication Standard requires” NTP and IARC information for such chemicals. (ISOR at 7, emphasis is OEHHA’s).

Appendix D is “mandatory,” because OSHA requires that all manufacturers provide SDSs. In addition, OSHA “requires” certain toxicological information in an SDS and in a particular format. Neither these words nor the SDS rule relates to chemical classifications as carcinogens. In 1989, 2011 and 2012, the Courts of Appeal analyzed a version of the HCS that contained the same SDS rule. If OEHHA’s new interpretation were legally justified, the courts would have said that OEHHA may refer to both classifications and information in the HCS for Proposition 65 listings. They did not, which precludes OEHHA from proposing its new interpretation.

4. **The 2012 HCS amendments are irrelevant to OEHHA’s listing authority and therefore cannot justify expanding its authority in Subsection (a)(2).**

OEHHA states on page 7 of its ISOR:

In March 2012, OSHA *extensively* amended the regulations contained in Title 29, C.F.R. section 1910.1200 *New Mandatory Appendix D* of the 2012 version . . . provides that a “safety data sheet (SDS) shall include the information specified in Table D.1”(emphasis added).

By emphasizing the words “extensively,” “new” and “shall,” OEHHA implies that the 2012 changes require and justify a new interpretation of its listing authority. There are several reasons why the 2012 changes do not change how OEHHA’s listing authority.

First, OSHA did not “extensively amend” the HCS from the standpoint of OEHHA’s authority under Proposition 65. OSHA amended the way chemicals are classified in the HCS. OEHHA does not classify chemicals when it refers to the HCS. Proposition 65 authorizes it only to rely on OSHA’s mandatory classifications of chemicals. In amending the way chemicals are classified, OSHA did eliminate several of the “floor lists” that OEHHA was permitted to list from, but this amendment does not change OEHHA’s listing authority to be able to list in a new way when it refers to the HCS. The courts have established that OEHHA’s authority is limited to the “floor lists.” OEHHA cannot expand its authority from listing by reference to mandatory chemical identifications to listing by reference to SDS information, even if what is required to be in an SDS is “mandatory.” See Cal. Gov’t Code § 11342.1 (all regulations “shall be within the scope of the authority conferred”) (2012).

Second, as analyzed above, Appendix D is not “new.” The HCS has always contained this purportedly “new” SDS rule OEHHA claims justifies a new interpretation, and OSHA simply amended SDS formatting requirements. Furthermore, OEHHA’s misplaced emphasis on the word “shall” is analytically flawed—the word refers to what is required to be employed on an SDS, not to how a chemical is identified as a carcinogen.

Finally, the people of California, through Proposition 65, give OEHHA its listing authority. Not OSHA. Not the HCS. The relevant language in Proposition 65 has not changed. OSHA’s 2012 HCS amendments therefore cannot be used to justify an expansion of OEHHA’ authority to list in a brand new way in order to be able to continue to list from the NTP’s RoC without scientific review. If OEHHA ever could have listed by referring to the SDS rule, then it would have been because Proposition 65 contained the word “information” in lieu of “identification,” and it would have been because the courts had established that this meant that OEHHA could list by reference to OSHA’s SDS information in lieu of OSHA’s mandatory classifications.

5. Subsection (a)(2) must be rewritten to permit OEHHA to list only from OSHA’s mandatory list of carcinogens in Subpart Z of the HCS.

The 2012 HCS provides that “[w]here OSHA has included cancer as a health hazard to be considered by classifiers for a chemical covered by 29 C.F.R. part 1910, Subpart Z, Toxic and Hazardous Substances, chemical manufacturers, importers, and employers shall classify the chemical as a carcinogen.” 29 C.F.R. § 1910.1200, App. A § A.6.4.2. This is the only “floor list” OEHHA may refer to for Proposition 65 listings. OEHHA must clearly state this in its proposed regulation.

6. **OEHHA is required under the California Administrative Procedure Act (“APA”) to choose the only two reasonable and legal alternatives.**

OEHHA states on page 4 of its ISOR:

One alternative to the proposed regulation that was considered by OEHHA was to refrain from proposing a regulation at all. This alternative was rejected because OEHHA believes that businesses subject to the Act should have the opportunity to know and understand the process by which OEHHA currently adds chemicals and substances to the Proposition 65 list via the Labor Code mechanism.

OEHHA is required to consider reasonable alternatives that are less burdensome and equally effective. Cal. Gov’t Code § 11346.2(b)(5)(A). It is required to make a specific determination “with supporting information” that “*no alternative considered by the agency would be . . . as effective and less burdensome to affected private persons than the adopted regulation.*” Id. at § 11346.9(a)(4) (emphasis added).

OEHHA’s justification for doing nothing is misleading because OEHHA does not “currently” add chemicals and substances to the Proposition 65 list by reference to SDS rules, so this proposal does not simply clarify OEHHA’s current procedures. When OEHHA then claims in its ISOR that the “the proposed regulation does not impose any new requirement upon any business,” and therefore that “the proposed regulatory action will not have a significant statewide adverse economic impact directly affecting businesses,” it also misleads the public into believing that its proposed regulation is cost neutral. It is neither. Any regulation that impermissibly allows an agency to assert its authority over members of the public who are not already subject to its authority necessarily imposes “new requirements” and potentially could have “adverse economic impacts,” particularly with respect to Proposition 65 and the significant irreparable effect of its warning requirements.

The only reasonable alternative to an unlawful regulation is to withdraw it. See id. See also id. at § 11346.3(a) (state agencies must assess potential adverse impacts of regulations to avoid the imposition of unreasonable regulations); § 11349.1 (Office of Administrative Law (OAL) is required to return proposed regulations if agencies do not make the necessary alternatives determination).

Proposed Subsection (a)(2) would circumvent the only reasonable and legal alternatives available to OEHHA: first, the Authoritative Bodies mechanism, which allows OEHHA to list from the NTP’s Report on Carcinogens (RoC) and the IARC Monographs; second, consideration by the Carcinogen Identification Committee (CIC).

The Authoritative Bodies mechanism is more reasonable because it requires OEHHA to consider scientifically valid data which were not considered by an authoritative body that show that there is insufficient evidence of carcinogenicity from studies in human or experimental animals. See Cal.

Code Regs. tit. 27, § 25306(e)-(g). This more robust and rigorous alternative offers the public a greater level of protection from unwarranted Proposition 65 listings. Likewise, submitting chemicals listed from the NTP's RoC to the CIC would better protect the public from unwarranted Proposition 65 listings.

Because the public would be denied the opportunity to object to OEHHA's imposed listings by reference to the proposed SDS rule, it is not reasonable that OEHHA would deny the public the benefits of and protections against potentially unwarranted listings afforded by the two existing legal and more reasonable alternatives. Thus, this proposed regulation fails the "reasonable alternatives" balancing requirement under Section 11346.2(b)(5)(A) of the California APA.

7. OEHHA again did not perform the required Economic Impact Analysis (EIA).

OEHHA misleads the public on page 3 into believing that it performed the required EIA:

"OEHHA also relied on the attached Economic Impact Analysis in developing the proposed regulation."

But on page 9 of the "Economic Impact Analysis," it's clear that OEHHA did not do one:

OEHHA finds there will be no economic impact related to this proposed regulatory language. The proposed regulation would not impose any costs because businesses are already subject to Proposition 65, nor would it propose any [sic] requirements on businesses. The proposed regulation simply clarifies the process and criteria used to list chemicals under Proposition 65.

OEHHA made the same two claims in the ISOR supporting the last version of this proposed regulation. When OEHHA's Chief Counsel, Carol Monahan-Cummings, was asked at the June 17, 2013 workshop regarding the prior version whether OEHHA had in fact performed the EIA, she admitted that it had not done one.

The APA requires that the economic impact of a regulation be assessed for adverse impact on business enterprises and individuals. Cal. Gov't Code § 11346.3(c)(1). An agency is required to assess how its proposal would affect the competitive advantages and disadvantages for businesses. Furthermore, if a proposed regulation could have an estimated economic impact in an amount exceeding \$50 million dollars, it is considered a "major regulation" and is subject to additional requirements. *Id.* at §§ 11346.3, 11343.548.

This proposed regulation gives OEHHA the authority to list chemicals from more sources than what Proposition 65 authorizes and without being required to review the underlying science. This significant broadening of OEHHA's scope of authority would necessarily increase the number of Proposition 65 listings and hence broaden Proposition 65's regulatory effect on businesses,

products, consumers and industry. Without scientific review of the listings, this proposed regulation is likely to require certain businesses to place false warnings on their products, adversely affecting those products, increasing prices, skewing markets and altering trade balances in industries such as agricultural packaging. There is a marginal economic impact from OEHHA's proposal, and OEHHA's assertion that businesses are already subject to Proposition 65 fails to acknowledge or address this marginal adverse economic impact.

OEHHA's proposed expansion of its authority to require a Proposition 65 warning on the basis of information that appears on an SDS could have profound, adverse economic consequences. SDS information is "inside the business" information for employers, employees and others with occupational skill and training who have contact with a chemical in a workplace setting and who require that information for handling or response. A Proposition 65 warning, however, goes "on the product" (or wall of a business) and is outside the context of an occupation or a workplace. OEHHA's proposed expansion of its authority in this rule would require an employer to warn to avoid lawsuits, even if the product would do no harm, solely because of SDS information. The Proposition 65 warning would be received by individuals without occupational safety training or expertise, and would lead them to reject the product because of the stigma of the Proposition 65 warning label, even though the product was not known to the state to cause cancer. The ramifications of the Proposition 65 stigma would reverberate outside California into the global economy where California products must compete. California citizens and employers would be deprived of making exports that would be deselected because of the improperly required Proposition 65 warning that was based on information on an SDS—not a classification by OSHA that the product is a carcinogen. Similarly, Californians would be deprived of the option to purchase these products because some manufacturers and producers would simply not sell in California if forced to put the Proposition 65 warning on their product that this rule would impermissibly require.

These are profound, adverse economic impacts, but OEHHA blithely announced that there was no economic impact of its proposed rule.

In the SIRC v. OEHHA litigation, OEHHA was made aware of the impacts of unwarranted Proposition 65 listings, which could immediately cause de-selection of styrene-based products in California industries generating billions of dollars, and it was also made aware that this would harm not only those who produce and use styrene-based products, but also consumers, the environment and the public health. See SIRC v. OEHHA, Sacramento Sup. Ct., Case No. 34-2009-0053089-CU-JR-GDS (2009). Its effect on packaging for agricultural products, for example, would have a significant adverse economic impact on the significant market worldwide for California table grapes.

OEHHA was aware of the potential economic impacts of this proposed regulation but did not perform the required economic analysis. OEHHA further was required to comply with the "major regulation" EIA provisions of the APA because it knew (or should have known) this proposed

regulation could have an estimated economic impact exceeding \$50 million. Failure to comply with the APA's EIA provisions nullifies a regulation. Kings Rehab. Center, Inc. v. Premo, 69 Cal. App. 4th 215, 217 (1999). OEHHA again has acted arbitrarily and abused its discretion by claiming "no economic impact" without performing the required economic impact analysis.

OEHHA and the public would begin to have a clear idea of the widespread impact of this proposed regulation if OEHHA were to perform an EIA prior to adoption of its regulation for each chemical from the NTP's listings that OEHHA now plans to propose to list on Proposition 65. There are currently chemicals under consideration by OEHHA for potential listing by reference to the NTP's RoC that OEHHA could have used in the required EIA to assess economic impact. The public is entitled to know the effect of such potential listings so that it may effectively comment on and participate in this regulatory process. See Cal. Gov't Code § 11340 et seq.

8. Subsection (a)(2) conflicts with and is contradictory to Proposition 65, the Labor Code, court decisions and existing statutory alternatives.

The APA requires that regulations be "consistent," which is defined as:

[B]eing in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions or other provisions of law.

Id. at § 11349 (d); 11349.1(a)(4); 11343.2. The APA further provides:

[N]o regulation adopted is valid or effective unless consistent with and not in conflict with the statute [a state agency implements] and reasonably necessary to effectuate the purpose of the statute.

Id. at 11342.2; 11350(b)(1). See Ontario Community Foundation, 35 Cal.3d 811, 816 (1984) (regulations that are at variance with the statute they implement "must be deemed to 'alter or amend the statute' and 'impair its scope' and [are] void") (quoting Woods v. Superior Court, 28 Cal.3d 668, 679 (1981)).

Subsection (a)(2) fails to comply with each of these requirements:

- It conflicts with Proposition 65's mandate to list chemicals under Proposition 65 only by reference to chemical "identifications;"
- It conflicts with court decisions providing that OEHHA is only permitted to list chemicals by reference to OSHA's mandatory "floor list" for carcinogen "identifications" or "classifications;"
- It conflicts with the Department of Industrial Relations' statutory scheme and its use of Labor Code section 6382(d) to list chemicals from OSHA's "listings" on the Director of

Industrial Relations' hazardous substances list only by reference to OSHA's mandatory chemical identification or classification "listings." See Cal. Labor Code § 6382(a) (providing that the Director's List is to be composed of substances "designated" in "listings" of other agencies).

- It conflicts with and is not in harmony with the Authoritative Bodies' mechanism or independent review of chemicals by the CIC;
- It could not be reasonably necessary to effectuate the purpose of Proposition 65 if it permits OEHHA to find that chemicals are "known to the state to cause cancer" when OSHA has not in fact "identified" or "classified" such chemicals as carcinogens in the HCS;
- It could not be reasonably necessary to effectuate the purpose of Proposition 65 if it is invalid under the case law, and if there are more reasonable alternatives.

B. THIS REGULATORY PROCESS AND PROPOSED SUBSECTION (a)(2) VIOLATE THE PUBLIC'S RIGHT TO DUE PROCESS UNDER THE LAW.

1. **Proposed Subsection (a)(2) is arbitrary and capricious and consistent with OEHHA's pattern in recent years of ignoring Proposition 65's statutory language, established case law, rigorous scientific review and public participation.**

The Fourteenth Amendment protects individuals from unreasonable, arbitrary and capricious laws and regulations by affording them due process under the law. See Goldberg v. Kelly, 397 U.S. 268 (1970). Hence, agencies are subject to administrative procedural rules to protect the public from regulations which have been promulgated without effective and meaningful notice and without effective opportunity to be heard. Armistead v. State Personnel Board, 22 Cal.3d 198, 204 (1978). Rules which are made behind closed doors without public input are null and void. Kings Rehab. Ctr., 69 Cal.App.4th at 217.

The California Supreme Court highlighted the importance of effective notice and opportunity to be heard in Armistead v. State Personnel Board:

A major aim of the APA was to provide a procedure whereby people to be affected may be heard on the merits of proposed rules. Yet we are here requested to give weight to section 525.11 in a controversy that pits the board against an individual member of exactly that class the APA sought to protect before rules like this are made effective. That, we think, would permit an agency to flout the APA by penalizing those who were entitled to notice and opportunity to be heard but received neither.

Under sections 11371(b), 11420 and 11440 of the APA, rules that interpret and implement other rules have no legal effect unless they have been promulgated in substantial compliance with the APA.

Therefore section 525.11 merits no weight as an agency interpretation. To hold otherwise might help perpetuate the problem that more than 20 years ago was identified in the First Report of the Senate Interim Committee on Administrative Regulations, *Supra*, as follows (at pp. 8-9):

“The committee is compelled to report to the Legislature that it has found many agencies which avoid the mandatory requirements of the Administrative Procedure Act of public notice, opportunity to be heard by the public, filing with the Secretary of State, and publication in the Administrative Code.

The committee has found that some agencies did not follow the act’s requirements because they were not aware of them; some agencies do not follow the act’s requirements because they believe they are exempt; at least one agency did not follow the act because it was too busy; some agencies feel the act’s requirements prevent them from administering the laws required to be administered by them; and many agencies . . . believe the function being performed was not in the realm of quasi-legislative powers.”

22 Cal.3d at 205-06.

OEHHA fails to provide effective notice of the purpose and effect of this proposed regulation. It misleads the public throughout this process by failing to state clearly in proposed Subsection (a)(2) exactly what it intends to do, failing to give meaningful and legal reasons for what it proposes to do, and misleading the public throughout its ISOR.

For example, by telling the public that it did not find any economic impact of its proposed regulation when it is apparent it did not perform an EIA, OEHHA has shown a complete disregard for the constitutional protections that the persons and businesses affected by OEHHA’s chemical listings are entitled to under the California and United States Constitutions.

It is unreasonable, arbitrary and capricious for OEHHA to propose to list substances by reference to the SDS rule. OEHHA has changed its mind too many times over the years to suit its own purposes without regard to what Proposition 65 provides and without regard to what the courts have established since 1989.

This is OEHHA’s fourth interpretation of its Labor Code listing authority since 2008. It proposed its first Labor Code regulation in 2008, and its interpretation then of its authority was more consistent

with the established holdings of the Courts of Appeal. See OEHHA, “Pre-Regulatory Workshop” slides, June 17, 2008, located on OEHHA’s website. Since then, OEHHA not only has changed its mind three times, as shown below, but it has repeatedly violated the due process rights of the public. For example:

- In 2009, OEHHA attempted to list styrene and vinyl acetate based on insufficient evidence in both humans and animals, despite the fact that Proposition 65 requires chemicals to be “known” to cause cancer, and despite that as far back as 1989, the Deukmejian Court explained throughout its decision that “known” to cause cancer would require at least “sufficient evidence” of carcinogenicity. See Deukmejian, 212 Cal.App.3d at 437, 439.
- In 2013, OEHHA attempted again to list styrene, this time based on a listing in the RoC that incorporated the *same* evidence the IARC had considered that the Court in 2012 had held was insufficient for a Proposition 65 listing, and despite that the RoC’s listing was being disputed nationwide. See January 4, 2103 Notice of Intent to List (NOIL) for styrene.
- OEHHA failed to tell the public in its January 4, 2013 NOIL for styrene that it had reinterpreted its Labor Code Listing authority by reference to the HCS – its second interpretation since 2009. OEHHA also failed to tell the public that the reason it had reinterpreted its listing authority was that OSHA had amended the HCS to delete the NTP’s RoC as a presumptive list of carcinogens, and that therefore it was proposing to list styrene based on a “choice” OSHA offers to chemical classifiers rather than a “mandatory classification.”
- In the Spring of 2013, OEHHA proposed a Labor Code regulation that ignored the clear language of Proposition 65 and the established holdings of the Courts of Appeal by proposing to list from the Director’s List, and by proposing to list from the NTP’s and IARC’s lists by reference to OSHA’s “choice” rather than by reference to OSHA’s “mandatory classification.” See May 17, 2013 Request for Public Participation and accompanying proposed regulation and Draft ISOR.
- In August of 2013, OEHHA entered into a consent decree with the Sierra Club in Sierra Club v. Brown, Alameda Sup. Ct., No. RGO7356881 (2007), in which it agreed through a settlement rather than by public participation to amend certain of its established procedures, such as to eliminate its “data call-in” public comment period provided for under the Authoritative Bodies mechanism. See July 12, 2013 Declaration of Susan F. Fiering and attached Stipulation for Entry of Partial Consent Judgment and Order Thereon at ¶ 3.21, located at <http://www.oehha.ca.gov/prop65/law/p65cases.html>.
- OEHHA ignored the decision of its CIC expert panel and the clear evidence showing a chemical does not cause cancer when it listed trichloroacetic acid on Proposition 65 in September of 2013.

- At a CIC meeting on December 5, 2013, Committee Member David A. Eastmond, Ph.D., asked OEHHA staff members why they had listed trichloroacetic acid on Proposition 65 under the Authoritative Bodies Mechanism (the chemical in fact had been listed via the Labor Code mechanism) after the CIC had met and reviewed this chemical and had determined specifically that it could not be listed. See Transcript of the Dec. 5, 2103 Meeting of the CIC at 172-73.
- Committee Member Eastmond stated: “Well, I remember this quite well. There were six positive animal studies, and we concluded that they were not relevant to humans. So we actually specifically addressed that issue on relevance. So unless there’s some other evidence that indicates these are relevant, it seems to me that it should not have been listed. . . . And yet someone else, another committee, makes a decision, and it automatically trumps the decision of this body.” Id. at 173-74.
- Staff Counsel Kammerer responded: “we have a ministerial duty to do it. So *if it’s determined by another method to cause cancer*, we follow that too. . . . We’re following Proposition 65, which we do not have the authority to alter the statute itself, and that’s the way the statute is written.” Id. at 173-75 (emphasis added).
- In response to another Committee Member’s questions, Dr. Zeise responded: “in this particular case, the International Agency for Research on Cancer reviewed the evidence for trichloroacetic acid, and we’re under the requirement for listing it via this Labor Code mechanism.” Id. at 175.
- OEHHA stated the following in its July 26, 2013 NOIL for trichloroacetic acid, which was issued after the 2012 HazCom amendments and during the last Labor Code listing regulatory process:
 - The listing was based on Labor Code section 6382(b)(1) and Labor Code section 6382(d)(2). OEHHA explained that “the Federal Hazard Communication *Standard relies on chemical designations made by IARC.*” (Emphasis added.)
 - Even though the CIC had thoroughly reviewed the science underlying the IARC’s listing and determined that it was not sufficient to find that trichloroacetic acid met the standard of “known to the state cause cancer,” OEHHA told the public: “OEHHA cannot consider scientific arguments concerning the weight or quality of the evidence considered by the IARC when it identified these chemicals and will not respond to such comments if they are submitted.”

- On February 7, 2014, presumably to augment its new interpretation in this regulatory process, OEHHA issued an NOIL under the Labor Code mechanism in part by reference to the SDS rule. See NOIL for Pulegone.
- On February 28, 2014, presumably to augment its new interpretation in this regulatory process, OEHHA issued another NOIL for chemicals under the Labor Code mechanism, again based in part by reference to the SDS rule. See NOIL for Pentosan Polysulfate Sodium, Pioglitazone and Triamterene.

OEHHA has frequently deprived the public of meaningful and effective public participation since it proposed its first Labor Code regulation. In some cases, it even precluded all public participation. In this case, OEHHA must withdraw its proposal to list by reference to SDS information, because not only is it not supported by the law, but it violates the due process rights of every person or business that could be subject to Proposition 65 listings of chemicals that are not classified as carcinogens by OSHA in the federal HCS.

2. **Subsection (a)(2) is invalid because it is being proposed through a process that is not transparent, certain or clear.**

OEHHA has not remained true to its commitment to the public to ensure that its regulatory requirements are carried out “in an open public process,” yet it assures the public in its ISOR that it has complied with due process.

PROBLEM BEING ADDRESSED BY THIS PROPOSED RULEMAKING

. . . . In order to ensure *transparency, certainty and clarity* for the general public, non-governmental organizations, and the business and enforcement communities, OEHHA is proposing a regulation for the Labor Code mechanism.

ISOR at 2 (emphasis added).

As shown above, Subsection (a)(2) is not transparent, certain or clear. OEHHA does not even mention SDSs in the proposed rule or that it is proposing for the first time ever to list chemicals based on the HCS’s SDS rule. The APA requires transparency, certainty and clarity in the regulation, in the ISOR and throughout the entire regulatory process. E.g., Cal. Gov’t Code § 11349.1.

OEHHA is not transparent, certain or clear in its ISOR. First, it waits to tell the public until page seven of its nine page document that it intends to list chemicals by reference to the SDS rule, and the only justification it gives for this novel listing method is to describe the SDS rule as “New Mandatory” Appendix D, and to highlight the words “shall” and “require.” ISOR at 7.

Second, OEHHA implies that this regulation is meant simply to inform the public how it has been listing chemicals under the Labor Code for 28 years, rather than being straightforward and explaining that Subsection (a)(2) reflects a new interpretation of Proposition 65, and rather than justifying why it is authorized to list under an interpretation that contradicts Proposition 65 and the established case law.

The following statements from the ISOR (with emphasis added) are misleading and confusing:

- “The purpose of this proposed regulation is to *clarify* and explain to interested parties *the way OEHHA identifies chemicals*” (p. 2);
- “OEHHA *looks* to the named sources identified in the specific subsections of the Labor Code” (p. 2);
- “This proposed regulation will provide information and clarification to the interested parties regarding *how OEHHA identifies chemicals*” (p. 3);
- “The proposed regulatory action *does not impose any new requirements upon private persons or business because it clarifies an existing process already used by OEHHA for listing and de-listing chemicals under Proposition 65*” (p. 4).

OEHHA does not currently list chemicals based on the SDS rule, and the courts never held that it may list in this fashion. OEHHA’s claim that it is merely proposing a rule that explains an established legal practice is misleading and false.

C. PROPOSED SUBSECTION (d) IS INVALID BECAUSE IT IS ARBITRARY AND INCONSISTENT, CONFLICTS WITH OTHER LISTING MECHANISMS AND VIOLATES DUE PROCESS UNDER THE LAW.

Proposed Subsection (d) is arbitrary and inconsistent because it is based on OEHHA’s assertion that the Labor Code Listing procedure is “essentially automatic,” but OEHHA does not propose in this subsection to “essentially automatically” remove chemicals from the Proposition 65 list that are no longer identified by reference in Labor Code Section 6382(b)(1) or Section 6382(d). See Cal. Gov’t Code §§ 11342.2, 11349.1(d)(4) (regulations must be consistent and must not cause a conflict in the statutory scheme). OEHHA proposes to the public that chemicals will automatically be placed on the Proposition 65 list if they are identified by reference to the Labor Code without any further scientific review, but it also proposes to the public that when those chemicals are no longer identified by reference to the Labor Code, it will not take them off the Proposition 65 list until they undergo a different procedure involving scientific review.

Moreover, OEHHA does not inform the public that its proposed delisting process means that chemicals could remain on the Proposition 65 list long after they have been delisted by the original listing body (and are not “known” to cause cancer).

It is arbitrary and inconsistent to deny the public the benefit of the Authoritative Bodies listing mechanism's scientific review process or the benefit of scientific review by OEHHA's own experts for listing chemicals but, within the same proposed regulation, to deny the public the prompt removal of chemicals from the Proposition 65 list if they are no longer proven to cause cancer so that OEHHA may submit them to scientific review. Id.

OEHHA justifies this arbitrary procedure with the following:

This subsection also explains that until the appropriate committee has considered whether the chemical must be delisted, the chemical remains on the list. This will reduce potential confusion that could occur if a chemical were to be de-listed, and then relisted again if the committee determines it is known to cause cancer or reproductive toxicity, and is consistent with the de-listing processes used for the other three listing mechanisms.

"Confusion" is not a reasonable justification to keep chemicals on the list which do not belong there based on Proposition 65's language. It is unlawful to require California businesses to be subject to Proposition 65's warning requirements for any period of time if a chemical is not proven to cause cancer. Moreover, it is alarmist and poor scientific practice for the public to be warned falsely that a product causes cancer. Finally, OEHHA must justify to the public why it aims to be consistent with the other listing mechanisms when delisting chemicals but why it is proposing to be inconsistent with the other listing mechanisms when listing chemicals. See Cal. Gov't Code § 11349.1(d)(4).

This proposed regulation would violate the due process rights of the businesses and individuals who are subject to Proposition 65 warning requirements by failing to delist chemicals immediately upon findings by the original listing sources that the chemicals no longer cause cancer. Proposed Subsection (d) is invalid because it arbitrarily and unlawfully subjects the public to two different procedures which could harm the public.

D. OEHHA MUST REWRITE THIS PROPOSED REGULATION TO KEEP OEHHA WITHIN THE BOUNDS OF ITS STATUTORY LISTING AUTHORITY AND TO ELIMINATE AMBIGUITIES AND INCONSISTENCIES.

- 1. OEHHA must completely rewrite Subsection (a)(2) so that it is clear and readily understandable, so that it accurately reflects OEHHA's listing power, and so that it eliminates any reference to "reproductive toxicity."**

There is no valid way to write Subsection (a)(2) as proposed by OEHHA because agencies are never authorized to adopt regulations that go beyond or do not accurately reflect their statutory authority and duties. As shown above, the only permissible way to write Subsection (a)(2) would

be to explain clearly within the regulation that OEHHA will list only by reference to OSHA's remaining "floor list."

OEHHA is obligated to explain to the public in its regulation what it does as an agency which carries out its Proposition 65 listing duties. The regulation—not the ISOR—must give the public the relevant information. OEHHA is obligated in its ISOR to explain the reasons and justifications for its regulation. The ISOR is not meant to contain the regulation's content.

Subsection (a)(2) is written as a statute—not as a permissible regulation explaining how OEHHA is permitted to list chemicals by reference to the HCS. The only transparent thing OEHHA has done is to draft its regulation as if it were a statute that broadens the scope of its listing authority. Moreover, OEHHA's regulation fails to satisfy the cardinal requirements of the APA. Agencies may promulgate regulations that reasonably interpret the statute they implement, explain specifically how they perform their authorized statutory duties or define terms that the public may not understand. See Cal. Gov't Code § 11342.2. Regulations must also be clear and consistent with an agency's delegation of authority. Id. at 11342.1-.2. They must not be confusing or use undefined terms, they must be readily understandable, they must not have more than one meaning, and they must avoid technical terms. Id. at 11342.580; 11349 et seq. OEHHA's regulation does not satisfy any of these requirements.

It does not interpret Proposition 65 or its reference to Labor Code sections 6382(b)(1) and (d), it does not explain how OEHHA performs its duties, and it does not define any terms in the statutes. Most importantly, it is impossible for the public to know which chemicals in the HCS OEHHA has the authority to list under Proposition 65.

Subsection (a)(2) must accurately state OEHHA's listing authority, and it also must provide an accurate citation to this floor list. Id. The 2012 HCS provides that "[w]here OSHA has included cancer as a health hazard to be considered by classifiers for a chemical covered by 29 C.F.R. Part 1910, Subpart Z, Toxic and Hazardous Substances, chemical manufacturers, importers, and employers shall classify the chemical as a carcinogen." 29 C.F.R. 1910.1200, App. A § A.6.4.2. This is the only "floor list" OEHHA may refer to for Proposition 65 listings. Any reference to the HCS SDS rule in this proposed Labor Code regulation is misplaced.

OEHHA also must also eliminate the words "reproductive toxicity" from Subsection (a)(2) because, as OEHHA acknowledges in the ISOR, OSHA has eliminated the ACGIH "floor list" from the 2012 HCS. This amendment has eliminated the ACGIH list as a reference for Proposition 65 reproductive toxicant listings. See ISOR at 7.

2. Subsection (a)(1) is ambiguous.

In Subsection (a)(1), OEHHA should move the phrase "based on sufficient animal or human evidence" to the end of the subsection, after the three subparts, and it should clarify the phrase to provide that OEHHA will not include chemicals on the Proposition 65 list from Groups 1, 2A or 2B

“unless the IARC chemical listings are based on at least sufficient human or sufficient animal evidence.” OEHHA’s Proposition 65 listing analysis cannot stop at the point of determining a chemical is on the IARC Group’s 1, 2A or 2B lists. It must go to the next step to find the chemical is known to the state to cause cancer based upon sufficient human or animal evidence.

E. SUBSECTION(a)(2) AND SECTION (d) WOULD VIOLATE FREEDOM OF SPEECH AND ARE PREEMPTED BY FEDERAL LAW.

1. Subsection (a)(2) and Section (d) would violate the public’s First Amendment Freedom of Speech rights.

OEHHA’s proposed regulation could have the effect of compelling businesses to provide false warnings on their products stating that the products are known to the state to cause cancer. The First Amendment right of freedom of speech includes the right not to speak. Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985). This right protects commercial speech, and it extends to statements of fact and opinion. Id.; Riley v. National Fed’n of the Blind, 487 U.S. 781, 797-98 (1988).

This regulation impermissibly expands OEHHA’s authority to list chemicals without consideration of the scientific evidence which may show that those chemicals do not cause cancer. California businesses could be required to make false and damaging statements about their products. They could be required to comply with OEHHA’s opinion that a chemical causes cancer rather than with a known fact. Proposition 65 is meant to protect against false warnings by requiring that OEHHA find that a chemical is “known” to cause cancer. This proposed regulation would violate the freedom of speech rights of businesses compelled to comply with it.

2. Subsection (a)(2) and Section (d) would be preempted by federal law.

The proposed provisions of this regulation that are based on a new interpretation of OEHHA’s listing authority by reference to SDS information will create a conflict between Proposition 65 and federal HCS requirements. When Proposition 65 was enacted, the HCS contained the floor lists referenced in 29 C.F.R. 1910.1200 subsections (d)(3) and (d)(4). Because Proposition 65 gave OEHHA the authority to list only the chemicals within the HCS that were required to be identified under the HCS as carcinogens, a listing under Proposition 65 and its corresponding warning requirements would not have conflicted with an HCS required identification and HCS warning requirements.

The amended HCS did not change OEHHA’s listing authority to list only from the HCS floor lists. If OEHHA lists instead by reference to OSHA’s SDS rule, chemical listings under Proposition 65 potentially would conflict with federal chemical classifications by chemical manufacturers. This could create conflicting workplace requirements and product label warnings.

OSHA amended the HCS in order to create uniformity within the United States and abroad:

The revisions to the HCS will standardize the hazard communication requirements for products used in U.S. workplaces, and thus provide employees with uniform and consistent hazard communication information. Secondly, because these revisions will harmonize the U.S. system with international norms, they will facilitate international trade.

OSHA, "Final Rule Summary," 77 FR at 17,604 (2012).

In 1997, OSHA approved of the incorporation of Proposition 65's occupational applications into the California Hazard Communication Standard to ensure that Proposition 65 would not create conflicts between the state and federal hazard communication standards and to ensure that Proposition 65 requirements would not place an undue burden on products distributed or used in interstate commerce. Hazard Communications, 62 Fed. Reg. 31,159-01 (1997).

OSHA reviewed the Proposition 65 statutory framework and corresponding OEHHA regulations which existed at that time and concluded that Proposition 65 would not create a conflict between the state and federal standards. Id. OSHA's decision was based in part on the assumption that because "Proposition 65's 'list' is based . . . upon the 'floor lists' used in the Federal standard," Proposition 65 listings based on a reference to the HCS would necessarily include the same chemicals that OSHA requires to be classified as hazardous. Id. at 31,170-74. (citing the Proposition 65 Labor Code listing mechanism).

A new OEHHA regulation which would permit conflicting chemical classifications will disrupt the uniformity and harmony which the federal HCS seeks to create and will undermine OSHA's 1997 approval of Proposition 65 within the state HCS.

In Shell Oil Co. v. U.S. Dept. of Labor, 106 F.Supp.2d 15, 21 (D.C. Dist. Ct. 2000), the Court addressed issues related to the incorporation of Proposition 65 into the state HCS. The Court found that OSHA's approval of Proposition 65 into the state plan was based on OSHA's conclusion that "there were in fact only a few technical differences between the regulatory scope of Proposition 65 and the federal standards." Id. The Court noted that one reason the two schemes were found to be consistent was that a chemical would not appear on either list unless statistically significant evidence based on valid scientific principles supported its classification. Id. To the extent that this proposed regulation allows OEHHA to list chemicals under Proposition 65 which are classified as carcinogens by the NTP but which would not be classified under the HCS criteria as carcinogens, it is preempted by federal law. See Id.

III. CONCLUSION

OEHHA has required the public for too many years and too many times to object to arbitrary and capricious actions that it has taken without regard to the economic interests of the California public, without regard to the legal and constitutional rights of the persons and businesses

affected, without regard to the established holdings of the California Courts of Appeal and without regard to the “rigorous science” it assures the public it will uphold.

The United States Supreme Court held last year that “[n]o matter how it is framed, the question a court faces when confronted with an agency’s interpretation of a statute it administers is always, simply, whether the agency has stayed within the bounds of its statutory authority.” City of Arlington v. Federal Communications Commission, 599 U.S. ___, 133 S. Ct. 1863 (2013) (emphasis added).

The California courts will not allow OEHHA to continue to exceed the bounds of its statutory authority. If OEHHA does not rewrite its proposed Labor Code regulation so that it accurately reflects its statutory listing authority, and so that the public can readily understand how OEHHA lists chemicals pursuant to the Labor Code listing mechanism, the courts will likely be required, once again, to explain to OEHHA what the phrase “substances within the scope of the federal Hazard Communication Standard” means.

Sincerely,



Harry Edward Grant
Margaret Cerrato-Blue³

of
RIDDELL WILLIAMS P.S.

cc: Mr. Scott Hakl, APTCO, LLC

Attachments: 1983 federal Hazard Communication Standard
1986 federal Hazard Communication Standard

³ California State Bar No. 162031

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section 15 of the Act and Agency procedures.

(j) *Effective dates.* The effective dates of the final standard are structured according to activity; that is, information being sent downstream must be prepared first, then other provisions of the hazard communication program are to be complied with by a later date. Chemical manufacturers and importers have two years in which to comply with the labeling of containers shipped downstream, and to provide material safety data sheets to manufacturing purchasers. Distributors must also begin transferring information downstream by this initial compliance date. All employers must be in compliance with all provisions of the standard within 2½ years.

V. Authority, Signature and the Standard

This document was prepared under the direction of Thorne G. Auchter, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210. Pursuant to Sections 6(b) and 8(g) of the Act, 29 CFR is hereby amended by adding a new § 1910.1200 to read as set forth below.

List of Subjects in 29 CFR Part 1910

Occupational safety and health, Hazard communication.

(Sec. 6(b), 8(c), and 8(g). Pub. L. 91-596, 84 Stat. 1593, 1599, 1600; 29 U.S.C. 655, 657; 29 CFR Part 1911; Secretary of Labor's Order No. 9-83 (48 FR 35736))

Signed at Washington, D.C. this 21st day of November 1983.

Thorne G. Auchter,

Assistant Secretary for Occupational Safety and Health.

PART 1910—[AMENDED]

Subpart 2 of Part 1910 of Title 29 of the Code of Federal Regulations (CFR) is hereby amended by adding a new § 1910.1200 to read as follows:

§ 1910.1200 Hazard communication.

(a) *Purpose.* (1) The purpose of this section is to ensure that the hazards of all chemicals produced or imported by chemical manufacturers or importers are evaluated, and that information concerning their hazards is transmitted to affected employers and employees within the manufacturing sector. This transmittal of information is to be accomplished by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, material safety data sheets and employee training.

(2) This occupational safety and health standard is intended to address comprehensively the issue of evaluating and communicating chemical hazards to employees in the manufacturing sector, and to preempt any state law pertaining to this subject. Any state which desires to assume responsibility in this area may only do so under the provisions of § 18 of the Occupational Safety and Health Act (29 U.S.C. 651 et seq.) which deals with state jurisdiction and state plans.

(b) *Scope and application.* (1) This section requires chemical manufacturers or importers to assess the hazards of chemicals which they produce or import, and all employers in SIC Codes 20 through 39 (Division D, Standard Industrial Classification Manual) to provide information to their employees about the hazardous chemicals to which they are exposed, by means of a hazard communication program, labels and other forms of warning, material safety data sheets, and information and training. In addition, this section requires distributors to transmit the required information to employers in SIC Codes 20-39.

(2) This section applies to any chemical which is known to be present in the workplace in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency.

(3) This section applies to laboratories only as follows:

(i) Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced;

(ii) Employers shall maintain any material safety data sheets that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible to laboratory employees; and,

(iii) Employers shall ensure that laboratory employees are apprised of the hazards of the chemicals in their workplaces in accordance with paragraph (h) of this section.

(4) This section does not require labeling of the following chemicals:

(i) Any pesticide as such term is defined in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Environmental Protection Agency;

(ii) Any food, food additive, color additive, drug, or cosmetic, including materials intended for use as ingredients in such products (e.g., flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and regulations issued under that Act, when

they are subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Food and Drug Administration;

(iii) Any distilled spirits (beverage alcohols), wine, or malt beverage intended for nonindustrial use, as such terms are defined in the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) and regulations issued under that Act, when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Bureau of Alcohol, Tobacco, and Firearms; and,

(iv) Any consumer product or hazardous substance as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) and Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.) respectively, when subject to a consumer product safety standard or labeling requirement of those Acts, or regulations issued under those Acts by the Consumer Product Safety Commission.

(5) This section does not apply to:

(i) Any hazardous waste as such term is defined by the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6901 et seq.), when subject to regulations issued under that Act by the Environmental Protection Agency;

(ii) Tobacco or tobacco products;

(iii) Wood or wood products;

(iv) Articles; and,

(v) Foods, drugs, or cosmetics intended for personal consumption by employees while in the workplace.

(c) *Definitions.* "Article" means a manufactured item: (i) Which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which does not release, or otherwise result in exposure to, a hazardous chemical under normal conditions of use.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Chemical" means any element, chemical compound or mixture of elements and/or compounds.

"Chemical manufacturer" means an employer in SIC Codes 20 through 39 with a workplace where chemical(s) are produced for use or distribution.

"Chemical name" means the scientific designation of a chemical in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS)

rules of nomenclature, or a name which will clearly identify the chemical for the purpose of conducting a hazard evaluation.

"Combustible liquid" means any liquid having a flashpoint at or above 100°F (37.8°C), but below 200°F (93.3°C), except any mixture having components with flashpoints of 200°F (93.3°C), or higher, the total volume of which make up 99 percent or more of the total volume of the mixture.

"Common name" means any designation or identification such as code name, code number, trade name, brand name or generic name used to identify a chemical other than by its chemical name.

"Compressed gas" means:

(i) A gas or mixture of gases having, in a container, an absolute pressure exceeding 40 psi at 70°F (21.1°C); or

(ii) A gas or mixture of gases having, in a container, an absolute pressure exceeding 104 psi at 130°F (54.4°C) regardless of the pressure at 70°F (21.1°C); or

(iii) A liquid having a vapor pressure exceeding 40 psi at 100°F (37.8°C) as determined by ASTM D-323-72.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems are not considered to be containers.

"Designated representative" means any individual or organization to whom an employee gives written authorization to exercise such employee's rights under this section. A recognized or certified collective bargaining agent shall be treated automatically as a designated representative without regard to written employee authorization.

"Director" means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

"Distributor" means a business, other than a chemical manufacturer or importer, which supplies hazardous chemicals to other distributors or to manufacturing purchasers.

"Employee" means a worker employed by an employer in a workplace in SIC Codes 20 through 39 who may be exposed to hazardous chemicals under normal operating conditions or foreseeable emergencies, including, but not limited to production workers, line supervisors, and repair or maintenance personnel. Office workers, grounds maintenance personnel, security personnel or non-resident management are generally not included, unless their job performance routinely

involves potential exposure to hazardous chemicals.

"Employer" means a person engaged in a business within SIC Codes 20 through 39 where chemicals are either used, or are produced for use or distribution.

"Explosive" means a chemical that causes a sudden, almost instantaneous release of pressure, gas, and heat when subjected to sudden shock, pressure, or high temperature.

"Exposure" or "exposed" means that an employee is subjected to a hazardous chemical in the course of employment through any route of entry (inhalation, ingestion, skin contact or absorption, etc.), and includes potential (e.g., accidental or possible) exposure.

"Flammable" means a chemical that falls into one of the following categories:

(i) "Aerosol, flammable" means an aerosol that, when tested by the method described in 16 CFR 1500.45, yields a flame projection exceeding 18 inches at full valve opening, or a flashback (a flame extending back to the valve) at any degree of valve opening;

(ii) "Gas, flammable" means:

(A) A gas that, at ambient temperature and pressure, forms a flammable mixture with air at a concentration of thirteen (13) percent by volume or less; or

(B) A gas that, at ambient temperature and pressure, forms a range of flammable mixtures with air wider than twelve (12) percent by volume, regardless of the lower limit;

(iii) "Liquid, flammable" means any liquid having a flashpoint below 100°F (37.8°C), except any mixture having components with flashpoints of 100°F (37.8°C) or higher, the total of which make up 99 percent or more of the total volume of the mixture.

(iv) "Solid, flammable" means a solid, other than a blasting agent or explosive as defined in § 1910.109(a), that is liable to cause fire through friction, absorption of moisture, spontaneous chemical change, or retained heat from manufacturing or processing, or which can be ignited readily and when ignited burns so vigorously and persistently as to create a serious hazard. A chemical shall be considered to be a flammable solid if, when tested by the method described in 16 CFR 1500.44, it ignites and burns with a self-sustained flame at a rate greater than one-tenth of an inch per second along its major axis.

"Flashpoint" means the minimum temperature at which a liquid gives off a vapor in sufficient concentration to ignite when tested as follows:

(i) Tagliabue Closed Tester (See American National Standard Method of Test for Flash Point by Tag Closed

Tester, Z11.24-1979 (ASTM D 56-79)) for liquids with a viscosity of less than 45 Saybolt Universal Seconds (SUS) at 100°F (37.8°C), that do not contain suspended solids and do not have a tendency to form a surface film under test; or

(ii) Pensky-Martens Closed Tester (see American National Standard Method of Test for Flash Point by Pensky-Martens Closed Tester, Z11.7-1979 (ASTM D 93-79)) for liquids with a viscosity equal to or greater than 45 SUS at 100°F (37.8°C), or that contain suspended solids, or that have a tendency to form a surface film under test; or

(iii) Setaflash Closed Tester (see American National Standard Method of Test for Flash Point by Setaflash Closed Tester (ASTM D 3278-78)).

Organic peroxides, which undergo autoaccelerating thermal decomposition, are excluded from any of the flashpoint determination methods specified above.

"Foreseeable emergency" means any potential occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which could result in an uncontrolled release of a hazardous chemical into the workplace.

"Hazard warning" means any words, pictures, symbols, or combination thereof appearing on a label or other appropriate form of warning which convey the hazards of the chemical(s) in the container(s).

"Hazardous chemical" means any chemical which is a physical hazard or a health hazard.

"Health hazard" means a chemical for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees. The term "health hazard" includes chemicals which are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents which act on the hematopoietic system, and agents which damage the lungs, skin, eyes, or mucous membranes. Appendix A provides further definitions and explanations of the scope of health hazards covered by this section, and Appendix B describes the criteria to be used to determine whether or not a chemical is to be considered hazardous for purposes of this standard.

"Identity" means any chemical or common name which is indicated on the material safety data sheet (MSDS) for the chemical. The identity used shall permit cross-references to be made

among the required list of hazardous chemicals, the label and the MSDS.

"Immediate use" means that the hazardous chemical will be under the control of and used only by the person who transfers it from a labeled container and only within the work shift in which it is transferred.

"Importer" means the first business with employees within the Customs Territory of the United States which receives hazardous chemicals produced in other countries for the purpose of supplying them to distributors or manufacturing purchasers within the United States.

"Label" means any written, printed, or graphic material displayed on or affixed to containers of hazardous chemicals.

"Manufacturing purchaser" means an employer with a workplace classified in SIC Codes 20 through 39 who purchases a hazardous chemical for use within that workplace.

"Material safety data sheet (MSDS)" means written or printed material concerning a hazardous chemical which is prepared in accordance with paragraph (g) of this section.

"Mixture" means any combination of two or more chemicals if the combination is not, in whole or in part, the result of a chemical reaction.

"Organic peroxide" means an organic compound that contains the bivalent -O-O- structure and which may be considered to be a structural derivative of hydrogen peroxide where one or both of the hydrogen atoms has been replaced by an organic radical.

"Oxidizer" means a chemical other than a blasting agent or explosive as defined in § 1910.109(a), that initiates or promotes combustion in other materials, thereby causing fire either of itself or through the release of oxygen or other gases.

"Physical hazard" means a chemical for which there is scientifically valid evidence that it is a combustible liquid, a compressed gas, explosive, flammable, an organic peroxide, an oxidizer, pyrophoric, unstable (reactive) or water-reactive.

"Produce" means to manufacture, process, formulate, or repackage.

"Pyrophoric" means a chemical that will ignite spontaneously in air at a temperature of 130° F (54.4° C) or below.

"Responsible party" means someone who can provide additional information on the hazardous chemical and appropriate emergency procedures, if necessary.

"Specific chemical identity" means the chemical name, Chemical Abstracts Service (CAS) Registry Number, or any other information that reveals the

precise chemical designation of the substance.

"Trade secret" means any confidential formula, pattern, process, device, information or compilation of information (including chemical name or other unique chemical identifier) that is used in an employer's business, and that gives the employer an opportunity to obtain an advantage over competitors who do not know or use it.

"Unstable (reactive)" means a chemical which in the pure state, or as produced or transported, will vigorously polymerize, decompose, condense, or will become self-reactive under conditions of shocks pressure or temperature.

"Use" means to package, handle, react, or transfer.

"Water-reactive" means a chemical that reacts with water to release a gas that is either flammable or presents a health hazard.

"Work area" means a room or defined space in a workplace where hazardous chemicals are produced or used, and where employees are present.

"Workplace" means an establishment at one geographical location containing one or more work areas.

(d) *Hazard determination.* (1) Chemical manufacturers and importers shall evaluate chemicals produced in their workplaces or imported by them to determine if they are hazardous. Employers are not required to evaluate chemicals unless they choose not to rely on the evaluation performed by the chemical manufacturer or importer for the chemical to satisfy this requirement.

(2) Chemical manufacturers, importers or employers evaluating chemicals shall identify and consider the available scientific evidence concerning such hazards. For health hazards, evidence which is statistically significant and which is based on at least one positive study conducted in accordance with established scientific principles is considered to be sufficient to establish a hazardous effect if the results of the study meet the definitions of health hazards in this section. Appendix A shall be consulted for the scope of health hazards covered, and Appendix B shall be consulted for the criteria to be followed with respect to the completeness of the evaluation, and the data to be reported.

(3) The chemical manufacturer, importer or employer evaluating chemicals shall treat the following sources as establishing that the chemicals listed in them are hazardous:

(i) 29 CFR Part 1910, Subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration (OSHA); or,

(ii) *Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment*, American Conference of Governmental Industrial Hygienists (ACGIH) (latest edition).

The chemical manufacturer, importer, or employer is still responsible for evaluating the hazards associated with the chemicals in these source lists in accordance with the requirements of the standard.

(4) Chemical manufacturers, importers and employers evaluating chemicals shall treat the following sources as establishing that a chemical is a carcinogen or potential carcinogen for hazard communication purposes:

(i) National Toxicology Program (NTP), *Annual Report on Carcinogens* (latest edition);

(ii) International Agency for Research on Cancer (IARC) *Monographs* (latest editions); or

(iii) 29 CFR Part 1910, Subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration.

Note.—The *Registry of Toxic Effects of Chemical Substances* published by the National Institute for Occupational Safety and Health indicates whether a chemical has been found by NTP or IARC to be a potential carcinogen.

(5) The chemical manufacturer, importer or employer shall determine the hazards of mixtures of chemicals as follows:

(i) If a mixture has been tested as a whole to determine its hazards, the results of such testing shall be used to determine whether the mixture is hazardous;

(ii) If a mixture has not been tested as a whole to determine whether the mixture is a health hazard, the mixture shall be assumed to present the same health hazards as do the components which comprise one percent (by weight or volume) or greater of the mixture, except that the mixture shall be assumed to present a carcinogenic hazard if it contains a component in concentrations of 0.1 percent or greater which is considered to be a carcinogen under paragraph (d)(4) of this section;

(iii) If a mixture has not been tested as a whole to determine whether the mixture is a physical hazard, the chemical manufacturer, importer, or employer may use whatever scientifically valid data is available to evaluate the physical hazard potential of the mixture; and

(iv) If the employer has evidence to indicate that a component present in the mixture in concentrations of less than

one percent (or in the case of carcinogens, less than 0.1 percent) could be released in concentrations which would exceed an established OSHA permissible exposure limit or ACGIH Threshold Limit Value, or could present a health hazard to employees in those concentrations, the mixture shall be assumed to present the same hazard.

(6) Chemical manufacturers, importers, or employers evaluating chemicals shall describe in writing the procedures they use to determine the hazards of the chemical they evaluate. The written procedures are to be made available, upon request, to employees, their designated representatives, the Assistant Secretary and the Director. The written description may be incorporated into the written hazard communication program required under paragraph (e) of this section.

(e) *Written hazard communication program.* (1) Employers shall develop and implement a written hazard communication program for their workplaces which at least describes how the criteria specified in paragraphs (f), (g), and (h) of this section for labels and other forms of warning, material safety data sheets, and employee information and training will be met, and which also includes the following:

(i) A list of the hazardous chemicals known to be present using an identity that is referenced on the appropriate

material safety data sheet (the list may be compiled for the workplace as a whole or for individual work areas);

(ii) The methods the employer will use to inform employees of the hazards of non-routine tasks (for example, the cleaning of reactor vessels), and the hazards associated with chemicals contained in unlabeled pipes in their work areas; and,

(iii) The methods the employer will use to inform any contractor employers with employees working in the employer's workplace of the hazardous chemicals their employees may be exposed to while performing their work, and any suggestions for appropriate protective measures.

(2) The employer may rely on an existing hazard communication program to comply with these requirements, provided that it meets the criteria established in this paragraph (e).

(3) The employer shall make the written hazard communication program available, upon request, to employees, their designated representatives, the Assistant Secretary and the Director, in accordance with the requirements of 29 CFR 1910.20(e).

(f) *Labels and other forms of warning.* (1) The chemical manufacturer, importer, or distributor shall ensure that each

container of hazardous chemicals leaving the workplace is labeled, tagged or marked with the following information:

(i) Identity of the hazardous chemical(s);

(ii) Appropriate hazard warnings; and

(iii) Name and address of the chemical manufacturer, importer, or other responsible party.

(2) Chemical manufacturers, importers, or distributors shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked in accordance with this section in a manner which does not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et seq.) and regulations issued under that Act by the Department of Transportation.

(3) If the hazardous chemical is regulated by OSHA in a substance-specific health standard, the chemical manufacturer, importer, distributor or employer shall ensure that the labels or other forms of warning used are in accordance with the requirements of that standard.

(4) Except as provided in paragraphs (f)(5) and (f)(6) the employer shall ensure that each container of hazardous chemicals in the workplace is labeled, tagged, or marked with the following information:

(i) Identity of the hazardous chemical(s) contained therein; and

(ii) Appropriate hazard warnings.

(5) The employer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys the information required by paragraph (f)(4) of this section to be on a label. The written materials shall be readily accessible to the employees in their work area throughout each work shift.

(6) The employer is not required to label portable containers into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(7) The employer shall not remove or deface existing labels on incoming containers of hazardous chemicals, unless the container is immediately marked with the required information.

(8) The employer shall ensure that labels or other forms of warning are legible, in English, and prominently displayed on the container, or readily available in the work area throughout each work shift. Employers having

employees who speak other languages may add the information in their language to the material presented, as long as the information is presented in English as well.

(9) The chemical manufacturer, importer, distributor or employer need not affix new labels to comply with this section if existing labels already convey the required information.

(g) *Material safety data sheets.* (1) Chemical manufacturers and importers shall obtain or develop a material safety data sheet for each hazardous chemical they produce or import. Employers shall have a material safety data sheet for each hazardous chemical which they use.

(2) Each material safety data sheet shall be in English and shall contain at least the following information:

(i) The identity used on the label, and, except as provided for in paragraph (f) of this section on trade secrets:

(A) If the hazardous chemical is a single substance, its chemical and common name(s);

(B) If the hazardous chemical is a mixture which has been tested as a whole to determine its hazards, the chemical and common name(s) of the ingredients which contribute to these known hazards, and the common name(s) of the mixture itself; or,

(C) If the hazardous chemical is a mixture which has not been tested as a whole:

(1) The chemical and common name(s) of all ingredients which have been determined to be health hazards, and which comprise 1% or greater of the composition, except that chemicals identified as carcinogens under paragraph (d)(4) of this section shall be listed if the concentrations are 0.1% or greater; and,

(2) The chemical and common name(s) of all ingredients which have been determined to present a physical hazard when present in the mixture;

(ii) Physical and chemical characteristics of the hazardous chemical (such as vapor pressure, flash point);

(iii) The physical hazards of the hazardous chemical, including the potential for fire, explosion, and reactivity;

(iv) The health hazards of the hazardous chemical, including signs and symptoms of exposure, and any medical conditions which are generally recognized as being aggravated by exposure to the chemical;

(v) The primary route(s) of entry;

(vi) The OSHA permissible exposure limit, ACGIH Threshold Limit Value, and any other exposure limit used or

recommended by the chemical manufacturer, importer, or employer preparing the material safety data sheet, where available;

(vii) Whether the hazardous chemical is listed in the National Toxicology Program (NTP) *Annual Report on Carcinogens* (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) *Monographs* (latest editions), or by OSHA;

(viii) Any generally applicable precautions for safe handling and use which are known to the chemical manufacturer, importer or employer preparing the material safety data sheet, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for clean-up of spills and leaks;

(ix) Any generally applicable control measures which are known to the chemical manufacturer, importer or employer preparing the material safety data sheet, such as appropriate engineering controls, work practices, or personal protective equipment;

(x) Emergency and first aid procedures;

(xi) The date of preparation of the material safety data sheet or the last change to it; and,

(xii) The name, address and telephone number of the chemical manufacturer, importer, employer or other responsible party preparing or distributing the material safety data sheet, who can provide additional information on the hazardous chemical and appropriate emergency procedures, if necessary.

(3) If no relevant information is found for any given category on the material safety data sheet, the chemical manufacturer, importer or employer preparing the material safety data sheet shall mark it to indicate that no applicable information was found.

(4) Where complex mixtures have similar hazards and contents (i.e. the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture), the chemical manufacturer, importer or employer may prepare one material safety data sheet to apply to all of these similar mixtures.

(5) The chemical manufacturer, importer or employer preparing the material safety data sheet shall ensure that the information recorded accurately reflects the scientific evidence used in making the hazard determination. If the chemical manufacturer, importer or employer becomes newly aware of any significant information regarding the hazards of a chemical, or ways to protect against the hazards, this new

information shall be added to the material safety data sheet within three months. If the chemical is not currently being produced or imported the chemical manufacturer or importer shall add the information to the material safety data sheet before the chemical is introduced into the workplace again.

(6) Chemical manufacturers or importers shall ensure that distributors and manufacturing purchasers of hazardous chemicals are provided an appropriate material safety data sheet with their initial shipment, and with the first shipment after a material safety data sheet is updated. The chemical manufacturer or importer shall either provide material safety data sheets with the shipped containers or send them to the manufacturing purchaser prior to or at the time of the shipment. If the material safety data sheet is not provided with the shipment, the manufacturing purchaser shall obtain one from the chemical manufacturer, importer, or distributor as soon as possible.

(7) Distributors shall ensure that material safety data sheets, and updated information, are provided to other distributors and manufacturing purchasers of hazardous chemicals.

(8) The employer shall maintain copies of the required material safety data sheets for each hazardous chemical in the workplace, and shall ensure that they are readily accessible during each work shift to employees when they are in their work area(s).

(9) Material safety data sheets may be kept in any form, including operating procedures, and may be designed to cover groups of hazardous chemicals in a work area where it may be more appropriate to address the hazards of a process rather than individual hazardous chemicals. However, the employer shall ensure that in all cases the required information is provided for each hazardous chemical, and is readily accessible during each work shift to employees when they are in their work area(s).

(10) Material safety data sheets shall also be made readily available, upon request, to designated representatives and to the Assistant Secretary, in accordance with the requirements of 29 CFR 1910.20(e). The Director shall also be given access to material safety data sheets in the same manner.

(h) *Employee information and training.* Employers shall provide employees with information and training on hazardous chemicals in their work area at the time of their initial assignment, and whenever a new hazard is introduced into their work area.

(1) *Information.* Employees shall be informed of:

(i) The requirements of this section;

(ii) Any operations in their work area where hazardous chemicals are present; and,

(iii) The location and availability of the written hazard communication program, including the required list(s) of hazardous chemicals, and material safety data sheets required by this section.

(2) *Training.* Employee training shall include at least:

(i) Methods and observations that may be used to detect the presence or release of a hazardous chemical in the work area (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released, etc.);

(ii) The physical and health hazards of the chemicals in the work area;

(iii) The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used; and,

(iv) The details of the hazard communication program developed by the employer, including an explanation of the labeling system and the material safety data sheet, and how employees can obtain and use the appropriate hazard information.

(i) *Trade secrets.* (1) The chemical manufacturer, importer or employer may withhold the specific chemical identity, including the chemical name and other specific identification of a hazardous chemical, from the material safety data sheet, provided that:

(i) The claim that the information withheld is a trade secret can be supported;

(ii) Information contained in the material safety data sheet concerning the properties and effects of the hazardous chemical is disclosed;

(iii) The material safety data sheet indicates that the specific chemical identity is being withheld as a trade secret; and,

(iv) The specific chemical identity is made available to health professionals, in accordance with the applicable provisions of this paragraph.

(2) Where a treating physician or nurse determines that a medical emergency exists and the specific chemical identity of a hazardous chemical is necessary for emergency or first-aid treatment, the chemical

manufacturer, importer, or employer shall immediately disclose the specific chemical identity of a trade secret chemical to that treating physician or nurse, regardless of the existence of a written statement of need or a confidentiality agreement. The chemical manufacturer, importer, or employer may require a written statement of need and confidentiality agreement, in accordance with the provisions of paragraphs (i) (3) and (4) of this section, as soon as circumstances permit.

(3) In non-emergency situations, a chemical manufacturer, importer, or employer shall, upon request, disclose a specific chemical identity, otherwise permitted to be withheld under paragraph (i)(1) of this section, to a health professional (i.e. physician, industrial hygienist, toxicologist, or epidemiologist) providing medical or other occupational health services to exposed employee(s) if:

(i) the request is in writing;
(ii) The request describes with reasonable detail one or more of the following occupational health needs for the information:

(A) To assess the hazards of the chemicals to which employees will be exposed;

(B) To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels;

(C) To conduct pre-assignment or periodic medical surveillance of exposed employees;

(D) To provide medical treatment to exposed employees;

(E) To select or assess appropriate personal protective equipment for exposed employees;

(F) To design or assess engineering controls or other protective measures for exposed employees; and,

(G) To conduct studies to determine the health effects of exposure.

(iii) The request explains in detail why the disclosure of the specific chemical identity is essential and that, in lieu thereof, the disclosure of the following information would not enable the health professional to provide the occupational health services described in paragraph (ii) of this section:

(A) The properties and effects of the chemical;

(B) Measures for controlling workers' exposure to the chemical;

(C) Methods of monitoring and analyzing worker exposure to the chemical; and,

(D) Methods of diagnosing and treating harmful exposures to the chemical;

(iv) The request includes a description of the procedures to be used to maintain

the confidentiality of the disclosed information; and,

(v) The health professional, and the employer or contractor of the health professional's services (i.e., downstream employer, labor organization, or individual employer), agree in a written confidentiality agreement that the health professional will not use the trade secret information for any purpose other than the health need(s) asserted and agree not to release the information under any circumstances other than to OSHA, as provided in paragraph (i)(8) of this section, except as authorized by the terms of the agreement or by the chemical manufacturer, importer, or employer.

(4) The confidentiality agreement authorized by paragraph (i)(3)(iv) of this section:

(i) May restrict the use of the information to the health purposes indicated in the written statement of need;

(ii) May provide for appropriate legal remedies in the event of a breach of the agreement, including stipulation of a reasonable pre-estimate of likely damages; and,

(iii) May not include requirements for the posting of a penalty bond.

(5) Nothing in this standard is meant to preclude the parties from pursuing non-contractual remedies to the extent permitted by law.

(6) If the health professional receiving the trade secret information decides that there is a need to disclose it to OSHA, the chemical manufacturer, importer, or employer who provided the information shall be informed by the health professional prior to, or at the same time as, such disclosure.

(7) If the chemical manufacturer, importer, or employer denies a written request for disclosure of a specific chemical identity, the denial must:

(i) Be provided to the health professional within thirty days of the request;

(ii) Be in writing;

(iii) Include evidence to support the claim that the specific chemical identity is a trade secret;

(iv) State the specific reasons why the request is being denied; and,

(v) Explain in detail how alternative information may satisfy the specific medical or occupational health need without revealing the specific chemical identity.

(8) The health professional whose request for information is denied under paragraph (i)(3) of this section may refer the request and the written denial of the request to OSHA for consideration.

(9) When a health professional refers the denial to OSHA under paragraph

(i)(8) of this section, OSHA shall consider the evidence to determine if:

(i) The chemical manufacturer, importer, or employer has supported the claim that the specific chemical identity is a trade secret;

(ii) The health professional has supported the claim that there is a medical or occupational health need for the information; and,

(iii) The health professional has demonstrated adequate means to protect the confidentiality.

(10) (i) If OSHA determines that the specific chemical identity requested under paragraph (i)(3) of this section is not a *bona fide* trade secret, or that it is a trade secret but the requesting health professional has a legitimate medical or occupational health need for the information, has executed a written confidentiality agreement, and has shown adequate means to protect the confidentiality of the information, the chemical manufacturer, importer, or employer will be subject to citation by OSHA.

(ii) If a chemical manufacturer, importer, or employer demonstrates to OSHA that the execution of a confidentiality agreement would not provide sufficient protection against the potential harm from the unauthorized disclosure of a trade secret specific chemical identity, the Assistant Secretary may issue such orders or impose such additional limitations or conditions upon the disclosure of the requested chemical information as may be appropriate to assure that the occupational health services are provided without an undue risk of harm to the chemical manufacturer, importer, or employer.

(11) If, following the issuance of a citation and any protective orders, the chemical manufacturer, importer, or employer continues to withhold the information, the matter is referable to the Occupational Safety and Health Review Commission for enforcement of the citation. In accordance with Commission rules, the Administrative Law Judge may review the citation and supporting documentation *in camera* or issue appropriate protective orders.

(12) Notwithstanding the existence of a trade secret claim, a chemical manufacturer, importer, or employer shall, upon request, disclose to the Assistant Secretary any information which this section requires the chemical manufacturer, importer, or employer to make available. Where there is a trade secret claim, such claim shall be made no later than at the time the information is provided to the Assistant Secretary so that suitable determinations of trade

secret status can be made and the necessary protections can be implemented.

(13) Nothing in this paragraph shall be construed as requiring the disclosure under any circumstances of process or percentage of mixture information which is trade secret.

(j) *Effective dates.* Employers shall be in compliance with this section within the following time periods:

(1) Chemical manufacturers and importers shall label containers of hazardous chemicals leaving their workplaces, and provide material safety data sheets with initial shipments by November 25, 1985.

(2) Distributors shall be in compliance with all provisions of this section applicable to them by November 25, 1985.

(3) Employers shall be in compliance with all provisions of this section by May 25, 1986, including initial training for all current employees.

Appendix A to § 1910.1200—Health Hazard Definitions (Mandatory)

Although safety hazards related to the physical characteristics of a chemical can be objectively defined in terms of testing requirements (e.g. flammability), health hazard definitions are less precise and more subjective. Health hazards may cause measurable changes in the body—such as decreased pulmonary function. These changes are generally indicated by the occurrence of signs and symptoms in the exposed employees—such as shortness of breath, a non-measurable, subjective feeling. Employees exposed to such hazards must be appraised of both the change in body function and the signs and symptoms that may occur to signal that change.

The determination of occupational health hazards is complicated by the fact that many of the effects or signs and symptoms occur commonly in non-occupationally exposed populations, so that effects of exposure are difficult to separate from normally occurring illnesses. Occasionally, a substance causes an effect that is rarely seen in the population at large, such as angiosarcomas caused by vinyl chloride exposure, thus making it easier to ascertain that the occupational exposure was the primary causative factor. More often, however, the effects are common, such as lung cancer. The situation is further complicated by the fact that most chemicals have not been adequately tested to determine their health hazard potential, and data do not exist to substantiate these effects.

There have been many attempts to categorize effects and to define them in

various ways. Generally, the terms "acute" and "chronic" are used to delineate between effects on the basis of severity or duration. "Acute" effects usually occur rapidly as a result of short-term exposures, and are of short duration. "Chronic" effects generally occur as a result of long-term exposure, and are of long duration.

The acute effects referred to most frequently are those defined by the American National Standards Institute (ANSI) standard for Precautionary Labeling of Hazardous Industrial Chemicals (Z129.1-1982)—irritation, corrosivity, sensitization and lethal dose. Although these are important health effects, they do not adequately cover the considerable range of acute effects which may occur as a result of occupational exposure, such as, for example, narcosis.

Similarly, the term chronic effect is often used to cover only carcinogenicity, teratogenicity, and mutagenicity. These effects are obvious a concern in the workplace, but again, do not adequately cover the area of chronic effects, excluding, for example, blood dyscrasias (such as anemia), chronic bronchitis and liver atrophy.

The goal of defining precisely, in measurable terms, every possible health effect that may occur in the workplace as a result of chemical exposures cannot realistically be accomplished. This does not negate the need for employees to be informed of such effects and protected from them.

Appendix B, which is also mandatory, outlines the principles and procedures of hazard assessment.

For purposes of this section, any chemicals which meet any of the following definitions, as determined by the criteria set forth in Appendix B are health hazards:

1. *Carcinogen:* A chemical is considered to be a carcinogen if:
(a) It has been evaluated by the International Agency for Research on Cancer (IARC), and found to be a carcinogen or potential carcinogen; or
(b) It is listed as a carcinogen or potential carcinogen in the *Annual Report on Carcinogens* published by the National Toxicology Program (NTP) (latest edition); or
(c) It is regulated by OSHA as a carcinogen.

2. *Corrosive:* A chemical that causes visible destruction of, or irreversible alterations in, living tissue by chemical action at the site of contact. For example, a chemical is considered to be corrosive if, when tested on the intact skin of albino rabbits by the method described by the U.S. Department of Transportation in Appendix A to 49 CFR

Part 173, it destroys or changes irreversibly the structure of the tissue at the site of contact following an exposure period of four hours. This term shall not refer to action on inanimate surfaces.

3. *Highly toxic:* A chemical falling within any of the following categories:

(a) A chemical that has a median lethal dose (LD₅₀) of 50 milligrams or less per kilogram of body weight when administered orally to albino rats weighing between 200 and 300 grams each.

(b) A chemical that has a median lethal dose (LD₅₀) of 200 milligrams or less per kilogram of body weight when administered by continuous contact for 24 hours (or less if death occurs within 24 hours) with the bare skin of albino rabbits weighing between two and three kilograms each.

(c) A chemical that has a median lethal concentration (LC₅₀) in air of 200 parts per million by volume or less of gas or vapor, or 2 milligrams per liter or less of mist, fume, or dust, when administered by continuous inhalation for one hour (or less if death occurs within one hour) to albino rats weighing between 200 and 300 grams each.

4. *Irritant:* A chemical, which is not corrosive, but which causes a reversible inflammatory effect on living tissue by chemical action at the site of contact. A chemical is a skin irritant if, when tested on the intact skin of albino rabbits by the methods of 16 CFR 1500.41 for four hours exposure or by other appropriate techniques, it results in an empirical score of five or more. A chemical is an eye irritant if so determined under the procedure listed in 16 CFR 1500.42 or other appropriate techniques.

5. *Sensitizer:* A chemical that causes a substantial proportion of exposed people or animals to develop an allergic reaction in normal tissue after repeated exposure to the chemical.

6. *Toxic:* A chemical falling within any of the following categories:

(a) A chemical that has a median lethal dose (LD₅₀) of more than 50 milligrams per kilogram but not more than 500 milligrams per kilogram of body weight when administered orally to albino rats weighing between 200 and 300 grams each.

(b) A chemical that has a median lethal dose (LD₅₀) of more than 200 milligrams per kilogram but not more than 1,000 milligrams per kilogram of body weight when administered by continuous contact for 24 hours (or less if death occurs within 24 hours) with the bare skin of albino rabbits weighing between two and three kilograms each.

(c) A chemical that has a median lethal concentration (LC₅₀) in air of

more than 200 parts per million but not more than 2,000 parts per million by volume of gas or vapor, or more than two milligrams per liter but not more than 20 milligrams per liter of mist, fume, or dust, when administered by continuous inhalation for one hour (or less if death occurs within one hour) to albino rats weighing between 200 and 300 grams each.

7. Target organ effects. The following

is a target organ categorization of effects which may occur, including examples of signs and symptoms and chemicals which have been found to cause such effects. These examples are presented to illustrate the range and diversity of effects and hazards found in the workplace, and the broad scope employers must consider in this area, but are not intended to be all-inclusive.

chemical manufacturer, importer, or employer may also report the results of other scientifically valid studies which tend to refute the findings of hazard.

Appendix C to § 1900.1200—Information Sources (Advisory)

The following is a list of available data sources which the chemical manufacturer, importer, or employer may wish to consult to evaluate the hazards of chemicals they produce or import:

- Any information in their own company files such as toxicity testing results or illness experience of company employees.
- Any information obtained from the supplier of the chemical, such as material safety data sheets or product safety bulletins.
- Any pertinent information obtained from the following source list (latest editions should be used):

Condensed Chemical Dictionary
Van Nostrand Reinhold Co., 135 West 50th Street, New York, NY 10020

The Merck Index: An Encyclopedia of Chemicals and Drugs
Merck and Company, Inc., 128 E. Lincoln Avenue, Rahway, NJ 07065

IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man
Geneva: World Health Organization, International Agency for Research on Cancer, 1972-1977. (Multivolume work), 49 Sheridan Street, Albany, New York

Industrial Hygiene and Toxicology, by F. A. Patty
John Wiley & Sons, Inc., New York, NY (Five volumes)

Clinical Toxicology of Commercial Products
Gleason, Gosselin and Hodge

Casarett and Doull's Toxicology; The Basic Science of Poisons
Doull, Klaassen, and Amdur, Macmillan Publishing Co., Inc., New York, NY

Industrial Toxicology, by Alice Hamilton and Harriet L. Hardy
Publishing Sciences Group, Inc., Acton, MA

Toxicology of the Eye, by W. Morion Grant
Charles C. Thomas, 301-327 East Lawrence Avenue, Springfield, IL

Recognition of Health Hazards in Industry
William A. Burgess, John Wiley and Sons, 605 Third Avenue, New York, NY 10158

Chemical Hazards of the Workplace
Nick H. Proctor and James P. Hughes, J. P. Lipincott Company, 6 Winchester Terrace, New York, NY 10022

Handbook of Chemistry and Physics
Chemical Rubber Company, 18901 Cranwood Parkway, Cleveland, OH 44128

Threshold Limit Values for Chemical Substances and Physical Agents in the Workroom Environment with Intended Changes
American Conference of Governmental Industrial Hygienists, 6500 Glenway Avenue, Bldg. D-5, Cincinnati, OH 45211

Note.—The following documents are on sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

a. Hepatotoxins:	Chemicals which produce liver damage.
Signs and Symptoms:	Jaundice; liver enlargement.
Chemicals:	Carbon tetrachloride; nitrosamines.
b. Nephrotoxins:	Chemicals which produce kidney damage.
Signs and Symptoms:	Edema; proteinuria.
Chemicals:	Halogenated hydrocarbons; uranium.
c. Neurotoxins:	Chemicals which produce their primary toxic effects on the nervous system.
Signs and Symptoms:	Narcosis; behavioral changes; decrease in motor functions.
Chemicals:	Mercury; carbon disulfide.
d. Agents which act on the blood or hematopoietic system:	Decrease hemoglobin function; deprive the body tissues of oxygen.
Signs and Symptoms:	Cyanosis; loss of consciousness.
Chemicals:	Carbon monoxide; cyanides.
e. Agents which damage the lung:	Chemicals which irritate or damage the pulmonary tissue.
Signs and Symptoms:	Cough; tightness in chest; shortness of breath.
Chemicals:	Silica; asbestos.
f. Reproductive toxins:	Chemicals which affect the reproductive capabilities including chromosomal damage (mutations) and effects on fetuses (teratogenesis).
Signs and Symptoms:	Birth defects; sterility.
Chemicals:	Lead; DBCP.
g. Cutaneous hazards:	Chemical which effect the dermal layer of the body.
Signs and Symptoms:	Defatting of the skin; rashes; irritation.
Chemicals:	Ketones; chlorinated compounds.
h. Eye hazards:	Chemicals which affect the eye or visual capacity.
Signs and Symptoms:	Conjunctivitis; corneal damage.
Chemicals:	Organic solvents; acids.

Appendix B to § 1900.1200—Hazard Determination (Mandatory)

The quality of a hazard communication program is largely dependent upon the adequacy and accuracy of the hazard determination. The hazard determination requirement of this standard is performance-oriented. Chemical manufacturers, importers, and employers evaluating chemicals are not required to follow any specific methods for determining hazards, but they must be able to demonstrate that they have adequately ascertained the hazards of the chemicals produced or imported in accordance with the criteria set forth in this Appendix.

Hazard evaluation is a process which relies heavily on the professional judgment of the evaluator, particularly in the area of chronic hazards. The performance-orientation of the hazard determination does diminish the duty of the chemical manufacturer, importer or employer to conduct a thorough evaluation, examining all relevant data and producing a scientifically defensible evaluation. For purposes of this standard, the following criteria shall be used in making hazard determinations that meet the requirements of this standard.

1. *Carcinogenicity:* As described in paragraph (d)(4) and Appendix A of this section, a determination by the National Toxicology Program, the International Agency for Research on Cancer, or OSHA that a chemical is a carcinogen or potential carcinogen will be considered conclusive evidence for purposes of this section.

2. *Human data:* Where available, epidemiological studies and case reports of adverse health effects shall be considered in the evaluation.

3. *Animal data:* Human evidence of health effects in exposed populations is generally not available for the majority of chemicals produced or used in the workplace. Therefore, the available results of toxicological testing in animal populations shall be used to predict the health effects that may be experienced by exposed workers. In particular, the definitions of certain acute hazards refer to specific animal testing results (see Appendix A).

4. *Adequacy and reporting of data:* The results of any studies which are designed and conducted according to established scientific principles, and which report statistically significant conclusions regarding the health effects of a chemical, shall be a sufficient basis for a hazard determination and reported on any material safety data sheet. The

Occupational Health Guidelines

NIOSH/OSHA (NIOSH Pub. No. 81-123)

NIOSH/OSHA Pocket Guide to Chemical Hazards

NIOSH Pub. No. 79-210

Registry of Toxic Effects of Chemical Substances

U.S. Department of Health and Human Services, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health (NIOSH Pub. No. 80-102)

The Industrial Environment—Its Evaluation and Control

U.S. Department of Health and Human Services, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health (NIOSH Pub. No. 74-117)

Miscellaneous Documents—National Institute for Occupational Safety and Health

1. Criteria for a recommended standard . . . Occupational Exposure to "—"
2. Special Hazard Reviews
3. Occupational Hazard Assessment
4. Current Intelligence Bulletins

Bibliographic Data Bases**Service Provider and File Name**

Bibliographic Retrieval Services (BRS),
Corporation Park, Bldg. 702, Scotia, New York 12302

AGRICOLA

BIOSIS PREVIEWS

CA CONDENSATES

CA SEARCH

DRUG INFORMATION.

MEDLARS

MEDOC

NTIS

POLLUTION ABSTRACTS

SCIENCE CITATION INDEX

SSIE

Lockheed—DIALOG, Lockheed Missiles & Space Company, Inc., P.O. Box 44481, San Francisco, CA 94144

AGRICOLA

BIOSIS PREV. 1972-PRESENT

BIOSIS PREV. 1969-71

CA CONDENSATES 1970-71

CA SEARCH 1972-78

CA SEARCH 1977-PRESENT

CHEMNAME

CONFERENCE PAPERS INDEX

FOOD SCIENCE & TECH. ABSTR.

FOODS ADLIBRA

INTL. PHARMACEUTICAL ABSTR.

NTIS

POLLUTION ABSTRACTS

SCISEARCH 1978-PRESENT

SCISEARCH 1974-77

SSIE CURRENT RESEARCH

SDC—ORBIT, SDC Search Service,

Department No. 2230, Pasadena, CA 91051

AGRICOLA**BIOCODES**

BIOSIS/BIO6973

CAS6771/CAS7276

CAS77

CHEMDEX

CONFERENCE

ENVIROLINE

LABORDOC

NTIS

POLLUTION

SSIE

Chemical Information System (CIS), Chemical Information Systems Inc., 7215 Yorke

Road, Baltimore, MD 21212

Structure & Nomenclature Search System

Acute Toxicity (RTECS)

Clinical Toxicology of Commercial

Products

Oil and Hazardous Materials Technical

Assistance Data System

National Library of Medicine, Department of

Health and Human Services, Public

Health Service, National Institutes of

Health, Bethesda, MD 20209

Toxicology Data Bank (TDB)

MEDLIN

TOXLINE

CANCERLIT

RTECS

[FR Doc. 83-31527 Filed 11-22-83; 8:45 am]

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tor, photoionization detection can be useful for locating high concentration pockets, in leak detection, and continuous ambient air monitoring. Both portable and stationary gas chromatographs are available with various types of detectors, including photoionization detectors. A gas chromatograph with a photoionization detector retains the photoionization sensitivity, but minimizes or eliminates interferences. For several GC/PID units, the sensitivity is in the 0.1-0.2 ppm EtO range. The GC/PID with microprocessors can sample up to 20 sample points sequentially, calculate and record data, and activate alarms or ventilation systems. Many are quite flexible and can be configured to meet the specific analysis needs for the workplace.

DuPont presented their laboratory validation data of the accuracy of the Qazi-Ketcham charcoal tube, the PCB charcoal tube, Miran 103 IR analyzer, 3M #3550 monitor and the Du Pont C-70 badge. Quoting Elbert V. Kring:

We also believe that OSHA's proposed accuracy in this standard is appropriate. At plus or minus 25 percent at one part per million, and plus or minus 35 percent below that. And, our data indicates there's only one monitoring method, right now, that we've tested thoroughly, that meets that accuracy requirements. That is the Du Pont Pro-Tek badge* * *. We also believe that this kind of data should be confirmed by another independent laboratory, using the same type dynamic chamber testing (Tr. 1470)

Additional data by an independent laboratory following their exact protocol was not submitted. However, information was submitted on comparisons and precision and accuracy of those monitoring procedures which indicate far better precision and accuracy of those monitoring procedures than that obtained by Du Pont (Ex. 4-20, 130, 11-68, 11-133, 130, 135A).

The accuracy of any method depends to a large degree upon the skills and experience of those who not only collect the samples but also those who analyze the samples. Even for methods that are collaboratively tested, some laboratories are closer to the true values than others. Some laboratories may meet the precision and accuracy requirements of the method; others may consistently far exceed them for the same method.

(Approved by the Office of Management and Budget under control number 1218-0108)

[49 FR 25796, June 22, 1984, as amended at 50 FR 9801, Mar. 12, 1985; 50 FR 41494, Oct. 11, 1985]

§ 1910.1200 Hazard communication.

(a) *Purpose.* (1) The purpose of this section is to ensure that the hazards of all chemicals produced or imported by chemical manufacturers or importers are evaluated, and that information concerning their hazards is transmitted to affected employers and employees within the manufacturing sector. This transmittal of information is to be accomplished by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, material safety data sheets and employee training.

(2) This occupational safety and health standard is intended to address comprehensively the issue of evaluating and communicating chemical hazards to employees in the manufacturing sector, and to preempt any state law pertaining to this subject. Any state which desires to assume responsibility in this area may only do so under the provisions of section 18 of the Occupational Safety and Health Act (29 U.S.C. 651 et. seq.) which deals with state jurisdiction and state plans.

(b) *Scope and application.* (1) This section requires chemical manufacturers or importers to assess the hazards of chemicals which they produce or import, and all employers in SIC Codes 20 through 39 (Division D, Standard Industrial Classification Manual) to provide information to their employees about the hazardous chemicals to which they are exposed, by means of a hazard communication program, labels and other forms of warning, material safety data sheets, and information and training. In addition, this section requires distributors to transmit the required information to employers in SIC Codes 20-39.

(2) This section applies to any chemical which is known to be present in the workplace in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency.

(3) This section applies to laboratories only as follows:

(i) Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced;

(ii) Employers shall maintain any material safety data sheets that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible to laboratory employees; and,

(iii) Employers shall ensure that laboratory employees are apprised of the hazards of the chemicals in their workplaces in accordance with paragraph (h) of this section.

(4) This section does not require labeling of the following chemicals:

(i) Any pesticide as such term is defined in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Environmental Protection Agency;

(ii) Any food, food additive, color additive, drug, or cosmetic, including materials intended for use as ingredients in such products (e.g., flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and regulations issued under that Act, when they are subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Food and Drug Administration;

(iii) Any distilled spirits (beverage alcohols), wine, or malt beverage intended for nonindustrial use, as such terms are defined in the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) and regulations issued under that Act, when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Bureau of Alcohol, Tobacco, and Firearms; and,

(iv) Any consumer product or hazardous substance as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) and Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.) respectively, when subject to a consumer product safety standard or labeling requirement of those Acts, or regulations issued under those Acts by the Consumer Product Safety Commission.

(5) This section does not apply to:

(i) Any hazardous waste as such term is defined by the Solid Waste Disposal Act, as amended by the Re-

source Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6901 et seq.), when subject to regulations issued under that Act by the Environmental Protection Agency;

(ii) Tobacco or tobacco products;

(iii) Wood or wood products;

(iv) Articles; and,

(v) Foods, drugs, or cosmetics intended for personal consumption by employees while in the workplace.

(c) *Definitions.* "Article" means a manufactured item: (i) Which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which does not release, or otherwise result in exposure to, a hazardous chemical under normal conditions of use.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Chemical" means any element, chemical compound or mixture of elements and/or compounds.

"Chemical manufacturer" means an employer in SIC Codes 20 through 39 with a workplace where chemical(s) are produced for use or distribution.

"Chemical name" means the scientific designation of a chemical in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS) rules of nomenclature, or a name which will clearly identify the chemical for the purpose of conducting a hazard evaluation.

"Combustible liquid" means any liquid having a flashpoint at or above 100°F (37.8°C), but below 200°F (93.3°C), except any mixture having components with flashpoints of 200°F (93.3°C), or higher, the total volume of which make up 99 percent or more of the total volume of the mixture.

"Common name" means any designation or identification such as code name, code number, trade name, brand name or generic name used to identify a chemical other than by its chemical name.

"Compressed gas" means:

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29 CFR Ch. XVII (7-1-86 Edition)

(i) A gas or mixture of gases having, in a container, an absolute pressure exceeding 40 psi at 70°F (21.1°C); or

(ii) A gas or mixture of gases having, in a container, an absolute pressure exceeding 104 psi at 130°F (54.4°C) regardless of the pressure at 70°F (21.1°C); or

(iii) A liquid having a vapor pressure exceeding 40 psi at 100°F (37.8°C) as determined by ASTM D-323-72.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems are not considered to be containers.

"Designated representative" means any individual or organization to whom an employee gives written authorization to exercise such employee's rights under this section. A recognized or certified collective bargaining agent shall be treated automatically as a designated representative without regard to written employee authorization.

"Director" means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

"Distributor" means a business, other than a chemical manufacturer or importer, which supplies hazardous chemicals to other distributors or to manufacturing purchasers.

"Employee" means a worker employed by an employer in a workplace in SIC Codes 20 through 39 who may be exposed to hazardous chemicals under normal operating conditions or foreseeable emergencies, including, but not limited to production workers, line supervisors, and repair or maintenance personnel. Office workers, grounds maintenance personnel, security personnel or non-resident management are generally not included, unless their job performance routinely involves potential exposure to hazardous chemicals.

"Employer" means a person engaged in a business within SIC Codes 20 through 39 where chemicals are either used, or are produced for use or distribution.

"Explosive" means a chemical that causes a sudden, almost instantaneous release of pressure, gas, and heat when subjected to sudden shock, pressure, or high temperature.

"Exposure" or "exposed" means that an employee is subjected to a hazardous chemical in the course of employment through any route of entry (inhalation, ingestion, skin contact or absorption, etc.), and includes potential (e.g., accidental or possible) exposure.

"Flammable" means a chemical that falls into one of the following categories:

(i) "Aerosol, flammable" means an aerosol that, when tested by the method described in 16 CFR 1500.45, yields a flame projection exceeding 18 inches at full valve opening, or a flashback (a flame extending back to the valve) at any degree of valve opening;

(ii) "Gas, flammable" means:

(A) A gas that, at ambient temperature and pressure, forms a flammable mixture with air at a concentration of thirteen (13) percent by volume or less; or

(B) A gas that, at ambient temperature and pressure, forms a range of flammable mixtures with air wider than twelve (12) percent by volume, regardless of the lower limit;

(iii) "Liquid, flammable" means any liquid having a flashpoint below 100°F (37.8°C), except any mixture having components with flashpoints of 100°F (37.8°C) or higher, the total of which make up 99 percent or more of the total volume of the mixture.

(iv) "Solid, flammable" means a solid, other than a blasting agent or explosive as defined in § 1910.109(a), that is liable to cause fire through friction, absorption of moisture, spontaneous chemical change, or retained heat from manufacturing or processing, or which can be ignited readily and when ignited burns so vigorously and persistently as to create a serious hazard. A chemical shall be considered to be a flammable solid if, when tested by the method described in 16 CFR 1500.44, it ignites and burns with a self-sustained flame at a rate greater than one-tenth of an inch per second along its major axis.

"Flashpoint" means the minimum temperature at which a liquid gives off

a vapor in sufficient concentration to ignite when tested as follows:

(i) Tagliabue Closed Tester (See American National Standard Method of Test for Flash Point by Tag Closed Tester, Z11.24-1979 (ASTM D 56-79)) for liquids with a viscosity of less than 45 Saybolt Universal Seconds (SUS) at 100°F (37.8°C), that do not contain suspended solids and do not have a tendency to form a surface film under test; or

(ii) Pensky-Martens Closed Tester (see American National Standard Method of Test for Flash Point by Pensky-Martens Closed Tester, Z11.7-1979 (ASTM D 93-79)) for liquids with a viscosity equal to or greater than 45 SUS at 100°F (37.8°C), or that contain suspended solids, or that have a tendency to form a surface film under test; or

(iii) Setaflash Closed Tester (see American National Standard Method of Test for Flash Point by Setaflash Closed Tester (ASTM D 3278-78)).

Organic peroxides, which undergo autoaccelerating thermal decomposition, are excluded from any of the flash-point determination methods specified above.

"Foreseeable emergency" means any potential occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which could result in an uncontrolled release of a hazardous chemical into the workplace.

"Hazard warning" means any words, pictures, symbols, or combination thereof appearing on a label or other appropriate form of warning which convey the hazards of the chemical(s) in the container(s).

"Hazardous chemical" means any chemical which is a physical hazard or a health hazard.

"Health hazard" means a chemical for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees. The term "health hazard" includes chemicals which are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins,

agents which act on the hematopoietic system, and agents which damage the lungs, skin, eyes, or mucous membranes. Appendix A provides further definitions and explanations of the scope of health hazards covered by this section, and Appendix B describes the criteria to be used to determine whether or not a chemical is to be considered hazardous for purposes of this standard.

"Identity" means any chemical or common name which is indicated on the material safety data sheet (MSDS) for the chemical. The identity used shall permit cross-references to be made among the required list of hazardous chemicals, the label and the MSDS.

"Immediate use" means that the hazardous chemical will be under the control of and used only by the person who transfers it from a labeled container and only within the work shift in which it is transferred.

"Importer" means the first business with employees within the Customs Territory of the United States which receives hazardous chemicals produced in other countries for the purpose of supplying them to distributors or manufacturing purchasers within the United States.

"Label" means any written, printed, or graphic material displayed on or affixed to containers of hazardous chemicals.

"Manufacturing purchaser" means an employer with a workplace classified in SIC Codes 20 through 39 who purchases a hazardous chemical for use within that workplace.

"Material safety data sheet (MSDS)" means written or printed material concerning a hazardous chemical which is prepared in accordance with paragraph (g) of this section.

"Mixture" means any combination of two or more chemicals if the combination is not, in whole or in part, the result of a chemical reaction.

"Organic peroxide" means an organic compound that contains the bivalent -O-O-structure and which may be considered to be a structural derivative of hydrogen peroxide where one or both of the hydrogen atoms has been replaced by an organic radical.

"Oxidizer" means a chemical other than a blasting agent or explosive as defined in § 1910.109(a), that initiates or promotes combustion in other materials, thereby causing fire either of itself or through the release of oxygen or other gases.

"Physical hazard" means a chemical for which there is scientifically valid evidence that it is a combustible liquid, a compressed gas, explosive, flammable, an organic peroxide, an oxidizer, pyrophoric, unstable (reactive) or water-reactive.

"Produce" means to manufacture, process, formulate, or repackage.

"Pyrophoric" means a chemical that will ignite spontaneously in air at a temperature of 130° F (54.4° C) or below.

"Responsible party" means someone who can provide additional information on the hazardous chemical and appropriate emergency procedures, if necessary.

"Specific chemical identity" means the chemical name, Chemical Abstracts Service (CAS) Registry Number, or any other information that reveals the precise chemical designation of the substance.

"Trade secret" means any confidential formula, pattern, process, device, information or compilation of information that is used in an employer's business, and that gives the employer an opportunity to obtain an advantage over competitors who do not know or use it. Appendix D sets out the criteria to be used in evaluating trade secrets.

"Unstable (reactive)" means a chemical which in the pure state, or as produced or transported, will vigorously polymerize, decompose, condense, or will become self-reactive under conditions of shocks pressure or temperature.

"Use" means to package, handle, react, or transfer.

"Water-reactive" means a chemical that reacts with water to release a gas that is either flammable or presents a health hazard.

"Work area" means a room or defined space in a workplace where hazardous chemicals are produced or used, and where employees are present.

"Workplace" means an establishment at one geographical location containing one or more work areas.

(d) *Hazard determination.* (1) Chemical manufacturers and importers shall evaluate chemicals produced in their workplaces or imported by them to determine if they are hazardous. Employers are not required to evaluate chemicals unless they choose not to rely on the evaluation performed by the chemical manufacturer or importer for the chemical to satisfy this requirement.

(2) Chemical manufacturers, importers or employers evaluating chemicals shall identify and consider the available scientific evidence concerning such hazards. For health hazards, evidence which is statistically significant and which is based on at least one positive study conducted in accordance with established scientific principles is considered to be sufficient to establish a hazardous effect if the results of the study meet the definitions of health hazards in this section. Appendix A shall be consulted for the scope of health hazards covered, and Appendix B shall be consulted for the criteria to be followed with respect to the completeness of the evaluation, and the data to be reported.

(3) The chemical manufacturer, importer or employer evaluating chemicals shall treat the following sources as establishing that the chemicals listed in them are hazardous:

(i) 29 CFR Part 1910, Subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration (OSHA); or,

(ii) *Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment*, American Conference of Governmental Industrial Hygienists (ACGIH) (latest edition).

The chemical manufacturer, importer, or employer is still responsible for evaluating the hazards associated with the chemicals in these source lists in accordance with the requirements of the standard.

(4) Chemical manufacturers, importers and employers evaluating chemicals shall treat the following sources as establishing that a chemical is a

carcinogen or potential carcinogen for hazard communication purposes:

(i) National Toxicology Program (NTP), *Annual Report on Carcinogens* (latest edition);

(ii) International Agency for Research on Cancer (IARC) *Monographs* (latest editions); or

(iii) 29 CFR Part 1910, Subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration.

NOTE: The *Registry of Toxic Effects of Chemical Substances* published by the National Institute for Occupational Safety and Health indicates whether a chemical has been found by NTP or IARC to be a potential carcinogen.

(5) The chemical manufacturer, importer or employer shall determine the hazards of mixtures of chemicals as follows:

(i) If a mixture has been tested as a whole to determine its hazards, the results of such testing shall be used to determine whether the mixture is hazardous;

(ii) If a mixture has not been tested as a whole to determine whether the mixture is a health hazard, the mixture shall be assumed to present the same health hazards as do the components which comprise one percent (by weight or volume) or greater of the mixture, except that the mixture shall be assumed to present a carcinogenic hazard if it contains a component in concentrations of 0.1 percent or greater which is considered to be a carcinogen under paragraph (d)(4) of this section;

(iii) If a mixture has not been tested as a whole to determine whether the mixture is a physical hazard, the chemical manufacturer, importer, or employer may use whatever scientifically valid data is available to evaluate the physical hazard potential of the mixture; and

(iv) If the employer has evidence to indicate that a component present in the mixture in concentrations of less than one percent (or in the case of carcinogens, less than 0.1 percent) could be released in concentrations which would exceed an established OSHA permissible exposure limit or ACGIH Threshold Limit Value, or could present a health hazard to employees

in those concentrations, the mixture shall be assumed to present the same hazard.

(6) Chemical manufacturers, importers, or employers evaluating chemicals shall describe in writing the procedures they use to determine the hazards of the chemical they evaluate. The written procedures are to be made available, upon request, to employees, their designated representatives, the Assistant Secretary and the Director. The written description may be incorporated into the written hazard communication program required under paragraph (e) of this section.

(e) *Written hazard communication program.* (1) Employers shall develop and implement a written hazard communication program for their workplaces which at least describes how the criteria specified in paragraphs (f), (g), and (h) of this section for labels and other forms of warning, material safety data sheets, and employee information and training will be met, and which also includes the following:

(i) A list of the hazardous chemicals known to be present using an identity that is referenced on the appropriate material safety data sheet (the list may be compiled for the workplace as a whole or for individual work areas);

(ii) The methods the employer will use to inform employees of the hazards of non-routine tasks (for example, the cleaning of reactor vessels), and the hazards associated with chemicals contained in unlabeled pipes in their work areas; and,

(iii) The methods the employer will use to inform any contractor employers with employees working in the employer's workplace of the hazardous chemicals their employees may be exposed to while performing their work, and any suggestions for appropriate protective measures.

(2) The employer may rely on an existing hazard communication program to comply with these requirements, provided that it meets the criteria established in this paragraph (e).

(3) The employer shall make the written hazard communication program available, upon request, to employees, their designated representatives, the Assistant Secretary and the

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Director, in accordance with the requirements of 29 CFR 1910.20(e).

(f) *Labels and other forms of warning.* (1) The chemical manufacturer, importer, or distributor shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged or marked with the following information:

(i) Identity of the hazardous chemical(s);

(ii) Appropriate hazard warnings; and

(iii) Name and address of the chemical manufacturer, importer, or other responsible party.

(2) Chemical manufacturers, importers, or distributors shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked in accordance with this section in a manner which does not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et seq.) and regulations issued under that Act by the Department of Transportation.

(3) If the hazardous chemical is regulated by OSHA in a substance-specific health standard, the chemical manufacturer, importer, distributor or employer shall ensure that the labels or other forms of warning used are in accordance with the requirements of that standard.

(4) Except as provided in paragraphs (f)(5) and (f)(6) the employer shall ensure that each container of hazardous chemicals in the workplace is labeled, tagged, or marked with the following information:

(i) Identity of the hazardous chemical(s) contained therein; and

(ii) Appropriate hazard warnings.

(5) The employer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys the information required by paragraph (f)(4) of this section to be on a label. The written materials shall be readily accessible to the employees in their work area throughout each work shift.

(6) The employer is not required to label portable containers into which

hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(7) The employer shall not remove or deface existing labels on incoming containers of hazardous chemicals, unless the container is immediately marked with the required information.

(8) The employer shall ensure that labels or other forms of warning are legible, in English, and prominently displayed on the container, or readily available in the work area throughout each work shift. Employers having employees who speak other languages may add the information in their language to the material presented, as long as the information is presented in English as well.

(9) The chemical manufacturer, importer, distributor or employer need not affix new labels to comply with this section if existing labels already convey the required information.

(g) *Material safety data sheets.* (1) Chemical manufacturers and importers shall obtain or develop a material safety data sheet for each hazardous chemical they produce or import. Employers shall have a material safety data sheet for each hazardous chemical which they use.

(2) Each material safety data sheet shall be in English and shall contain at least the following information:

(i) The identity used on the label, and, except as provided for in paragraph (f) of this section on trade secrets:

(A) If the hazardous chemical is a single substance, its chemical and common name(s);

(B) If the hazardous chemical is a mixture which has been tested as a whole to determine its hazards, the chemical and common name(s) of the ingredients which contribute to these known hazards, and the common name(s) of the mixture itself; or,

(C) If the hazardous chemical is a mixture which has not been tested as a whole:

(1) The chemical and common name(s) of all ingredients which have been determined to be health hazards, and which comprise 1% or greater of the composition, except that chemi-

cals identified as carcinogens under paragraph (d)(4) of this section shall be listed if the concentrations are 0.1% or greater; and,

(2) The chemical and common name(s) of all ingredients which have been determined to present a physical hazard when present in the mixture;

(ii) Physical and chemical characteristics of the hazardous chemical (such as vapor pressure, flash point);

(iii) The physical hazards of the hazardous chemical, including the potential for fire, explosion, and reactivity;

(iv) The health hazards of the hazardous chemical, including signs and symptoms of exposure, and any medical conditions which are generally recognized as being aggravated by exposure to the chemical;

(v) The primary route(s) of entry;

(vi) The OSHA permissible exposure limit, ACGIH Threshold Limit Value, and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the material safety data sheet, where available;

(vii) Whether the hazardous chemical is listed in the National Toxicology Program (NTP) *Annual Report on Carcinogens* (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) *Monoographs* (latest editions), or by OSHA;

(viii) Any generally applicable precautions for safe handling and use which are known to the chemical manufacturer, importer or employer preparing the material safety data sheet, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for clean-up of spills and leaks;

(ix) Any generally applicable control measures which are known to the chemical manufacturer, importer or employer preparing the material safety data sheet, such as appropriate engineering controls, work practices, or personal protective equipment;

(x) Emergency and first aid procedures;

(xi) The date of preparation of the material safety data sheet or the last change to it; and,

(xii) The name, address and telephone number of the chemical manufacturer, importer, employer or other responsible party preparing or distributing the material safety data sheet, who can provide additional information on the hazardous chemical and appropriate emergency procedures, if necessary.

(3) If no relevant information is found for any given category on the material safety data sheet, the chemical manufacturer, importer or employer preparing the material safety data sheet shall mark it to indicate that no applicable information was found.

(4) Where complex mixtures have similar hazards and contents (i.e. the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture), the chemical manufacturer, importer or employer may prepare one material safety data sheet to apply to all of these similar mixtures.

(5) The chemical manufacturer, importer or employer preparing the material safety data sheet shall ensure that the information recorded accurately reflects the scientific evidence used in making the hazard determination. If the chemical manufacturer, importer or employer becomes newly aware of any significant information regarding the hazards of a chemical, or ways to protect against the hazards, this new information shall be added to the material safety data sheet within three months. If the chemical is not currently being produced or imported the chemical manufacturer or importer shall add the information to the material safety data sheet before the chemical is introduced into the workplace again.

(6) Chemical manufacturers or importers shall ensure that distributors and manufacturing purchasers of hazardous chemicals are provided an appropriate material safety data sheet with their initial shipment, and with the first shipment after a material safety data sheet is updated. The chemical manufacturer or importer shall either provide material safety data sheets with the shipped containers or send them to the manufacturing purchaser prior to or at the time of the shipment. If the material safety

data sheet is not provided with the shipment, the manufacturing purchaser shall obtain one from the chemical manufacturer, importer, or distributor as soon as possible.

(7) Distributors shall ensure that material safety data sheets, and updated information, are provided to other distributors and manufacturing purchasers of hazardous chemicals.

(8) The employer shall maintain copies of the required material safety data sheets for each hazardous chemical in the workplace, and shall ensure that they are readily accessible during each work shift to employees when they are in their work area(s).

(9) Material safety data sheets may be kept in any form, including operating procedures, and may be designed to cover groups of hazardous chemicals in a work area where it may be more appropriate to address the hazards of a process rather than individual hazardous chemicals. However, the employer shall ensure that in all cases the required information is provided for each hazardous chemical, and is readily accessible during each work shift to employees when they are in their work area(s).

(10) Material safety data sheets shall also be made readily available, upon request, to designated representatives and to the Assistant Secretary, in accordance with the requirements of 29 CFR 1910.20(e). The Director shall also be given access to material safety data sheets in the same manner.

(h) *Employee information and training.* Employers shall provide employees with information and training on hazardous chemicals in their work area at the time of their initial assignment, and whenever a new hazard is introduced into their work area.

(1) *Information.* Employees shall be informed of:

(i) The requirements of this section;

(ii) Any operations in their work area where hazardous chemicals are present; and,

(iii) The location and availability of the written hazard communication program, including the required list(s) of hazardous chemicals, and material safety data sheets required by this section.

(2) *Training.* Employee training shall include at least:

(i) Methods and observations that may be used to detect the presence or release of a hazardous chemical in the work area (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released, etc.);

(ii) The physical and health hazards of the chemicals in the work area;

(iii) The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used; and,

(iv) The details of the hazard communication program developed by the employer, including an explanation of the labeling system and the material safety data sheet, and how employees can obtain and use the appropriate hazard information.

(i) *Trade secrets.* (1) The chemical manufacturer, importer or employer may withhold the specific chemical identity, including the chemical name and other specific identification of a hazardous chemical, from the material safety data sheet, provided that:

(i) The claim that the information withheld is a trade secret can be supported;

(ii) Information contained in the material safety data sheet concerning the properties and effects of the hazardous chemical is disclosed;

(iii) The material safety data sheet indicates that the specific chemical identity is being withheld as a trade secret; and,

(iv) The specific chemical identity is made available to health professionals, employees, and designated representatives, in accordance with the applicable provisions of this paragraph.

(2) Where a treating physician or nurse determines that a medical emergency exists and the specific chemical identity of a hazardous chemical is necessary for emergency or first-aid treatment, the chemical manufacturer, importer, or employer shall immediately disclose the specific chemical

identity of a trade secret chemical to that treating physician or nurse, regardless of the existence of a written statement of need or a confidentiality agreement. The chemical manufacturer, importer, or employer may require a written statement of need and confidentiality agreement, in accordance with the provisions of paragraphs (i)(3) and (4) of this section, as soon as circumstances permit.

(3) In non-emergency situations, a chemical manufacturer, importer, or employer shall, upon request, disclose a specific chemical identity, otherwise permitted to be withheld under paragraph (i)(1) of this section, to a health professional (i.e. physician, industrial hygienist, toxicologist, or epidemiologist) providing medical or other occupational health services to exposed employee(s), and to employees or designated representatives, if:

(i) the request is in writing;

(ii) The request describes with reasonable detail one or more of the following occupational health needs for the information:

(A) To assess the hazards of the chemicals to which employees will be exposed;

(B) To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels;

(C) To conduct pre-assignment or periodic medical surveillance of exposed employees;

(D) To provide medical treatment to exposed employees;

(E) To select or assess appropriate personal protective equipment for exposed employees;

(F) To design or assess engineering controls or other protective measures for exposed employees; and,

(G) To conduct studies to determine the health effects of exposure.

(iii) The request explains in detail why the disclosure of the specific chemical identity is essential and that, in lieu thereof, the disclosure of the following information to the health professional, employee, or designated representative, would not satisfy the purposes described in paragraph (i)(3)(ii) of this section:

(A) The properties and effects of the chemical;

(B) Measures for controlling workers' exposure to the chemical;

(C) Methods of monitoring and analyzing worker exposure to the chemical; and,

(D) Methods of diagnosing and treating harmful exposures to the chemical;

(iv) The request includes a description of the procedures to be used to maintain the confidentiality of the disclosed information; and,

(v) The health professional, and the employer or contractor of the services of the health professional (i.e. downstream employer, labor organization, or individual employee), employee, or designated representative, agree in a written confidentiality agreement that the health professional, employee, or designated representative, will not use the trade secret information for any purpose other than the health need(s) asserted and agree not to release the information under any circumstances other than to OSHA, as provided in paragraph (i)(6) of this section, except as authorized by the terms of the agreement or by the chemical manufacturer, importer, or employer.

(4) The confidentiality agreement authorized by paragraph (i)(3)(iv) of this section:

(i) May restrict the use of the information to the health purposes indicated in the written statement of need;

(ii) May provide for appropriate legal remedies in the event of a breach of the agreement, including stipulation of a reasonable pre-estimate of likely damages; and,

(iii) May not include requirements for the posting of a penalty bond.

(5) Nothing in this standard is meant to preclude the parties from pursuing non-contractual remedies to the extent permitted by law.

(6) If the health professional, employee, or designated representative receiving the trade secret information decides that there is a need to disclose it to OSHA, the chemical manufacturer, importer, or employer who provided the information shall be informed by the health professional, employee, or designated representative prior to, or at the same time as, such disclosure.

(7) If the chemical manufacturer, importer, or employer denies a written request for disclosure of a specific chemical identity, the denial must:

(i) Be provided to the health professional, employee, or designated representative, within thirty days of the request;

(ii) Be in writing;

(iii) Include evidence to support the claim that the specific chemical identity is a trade secret;

(iv) State the specific reasons why the request is being denied; and,

(v) Explain in detail how alternative information may satisfy the specific medical or occupational health need without revealing the specific chemical identity.

(8) The health professional, employee, or designated representative, whose request for information is denied under paragraph (i)(3) of this section may refer the request and the written denial of the request to OSHA for consideration.

(9) When a health professional, employee, or designated representative refers the denial to OSHA under paragraph (i)(8) of this section, OSHA shall consider the evidence to determine if:

(i) The chemical manufacturer, importer, or employer has supported the claim that the specific chemical identity is a trade secret;

(ii) The health professional, employee, or designated representative, has supported the claim that there is a medical or occupational health need for the information; and

(iii) The health professional, employee, or designated representative, has demonstrated adequate means to protect the confidentiality.

(10)(i) If OSHA determines that the specific chemical identity requested under paragraph (i)(3) of this section is not a *bona fide* trade secret, or that it is a trade secret, but the requesting health professional, employee, or designated representative has a legitimate medical or occupational health need for the information, has executed a written confidentiality agreement, and has shown adequate means to protect the confidentiality of the information, the chemical manufacturer, importer,

or employer will be subject to citation by OSHA.

(ii) If a chemical manufacturer, importer, or employer demonstrates to OSHA that the execution of a confidentiality agreement would not provide sufficient protection against the potential harm from the unauthorized disclosure of a trade secret specific chemical identity, the Assistant Secretary may issue such orders or impose such additional limitations or conditions upon the disclosure of the requested chemical information as may be appropriate to assure that the occupational health services are provided without an undue risk of harm to the chemical manufacturer, importer, or employer.

(11) If, following the issuance of a citation and any protective orders, the chemical manufacturer, importer, or employer continues to withhold the information, the matter is referable to the Occupational Safety and Health Review Commission for enforcement of the citation. In accordance with Commission rules, the Administrative Law Judge may review the citation and supporting documentation *in camera* or issue appropriate protective orders.

(12) Notwithstanding the existence of a trade secret claim, a chemical manufacturer, importer, or employer shall, upon request, disclose to the Assistant Secretary any information which this section requires the chemical manufacturer, importer, or employer to make available. Where there is a trade secret claim, such claim shall be made no later than at the time the information is provided to the Assistant Secretary so that suitable determinations of trade secret status can be made and the necessary protections can be implemented.

(13) Nothing in this paragraph shall be construed as requiring the disclosure under any circumstances of process or percentage of mixture information which is trade secret.

(j) *Effective dates.* Employers shall be in compliance with this section within the following time periods:

(1) Chemical manufacturers and importers shall label containers of hazardous chemicals leaving their workplaces, and provide material safety

data sheets with initial shipments by November 25, 1985.

(2) Distributors shall be in compliance with all provisions of this section applicable to them by November 25, 1985.

(3) Employers shall be in compliance with all provisions of this section by May 25, 1986, including initial training for all current employees.

APPENDIX A TO § 1910.1200—HEALTH HAZARD DEFINITIONS (MANDATORY)

Although safety hazards related to the physical characteristics of a chemical can be objectively defined in terms of testing requirements (e.g. flammability), health hazard definitions are less precise and more subjective. Health hazards may cause measurable changes in the body—such as decreased pulmonary function. These changes are generally indicated by the occurrence of signs and symptoms in the exposed employees—such as shortness of breath, a non-measurable, subjective feeling. Employees exposed to such hazards must be apprised of both the change in body function and the signs and symptoms that may occur to signal that change.

The determination of occupational health hazards is complicated by the fact that many of the effects or signs and symptoms occur commonly in non-occupationally exposed populations, so that effects of exposure are difficult to separate from normally occurring illnesses. Occasionally, a substance causes an effect that is rarely seen in the population at large, such as angiosarcomas caused by vinyl chloride exposure, thus making it easier to ascertain that the occupational exposure was the primary causative factor. More often, however, the effects are common, such as lung cancer. The situation is further complicated by the fact that most chemicals have not been adequately tested to determine their health hazard potential, and data do not exist to substantiate these effects.

There have been many attempts to categorize effects and to define them in various ways. Generally, the terms "acute" and "chronic" are used to delineate between effects on the basis of severity or duration. "Acute" effects usually occur rapidly as a result of short-term exposures, and are of short duration. "Chronic" effects generally occur as a result of long-term exposure, and are of long duration.

The acute effects referred to most frequently are those defined by the American National Standards Institute (ANSI) standard for Precautionary Labeling of Hazardous Industrial Chemicals (Z129.1-1982)—irritation, corrosivity, sensitization and lethal dose. Although these are important health

effects, they do not adequately cover the considerable range of acute effects which may occur as a result of occupational exposure, such as, for example, narcosis.

Similarly, the term chronic effect is often used to cover only carcinogenicity, teratogenicity, and mutagenicity. These effects are obvious a concern in the workplace, but again, do not adequately cover the area of chronic effects, excluding, for example, blood dyscrasias (such as anemia), chronic bronchitis and liver atrophy.

The goal of defining precisely, in measurable terms, every possible health effect that may occur in the workplace as a result of chemical exposures cannot realistically be accomplished. This does not negate the need for employees to be informed of such effects and protected from them.

Appendix B, which is also mandatory, outlines the principles and procedures of hazard assessment.

For purposes of this section, any chemicals which meet any of the following definitions, as determined by the criteria set forth in Appendix B are health hazards:

1. *Carcinogen*: A chemical is considered to be a carcinogen if:

(a) It has been evaluated by the International Agency for Research on Cancer (IARC), and found to be a carcinogen or potential carcinogen; or

(b) It is listed as a carcinogen or potential carcinogen in the *Annual Report on Carcinogens* published by the National Toxicology Program (NTP) (latest edition); or,

(c) It is regulated by OSHA as a carcinogen.

2. *Corrosive*: A chemical that causes visible destruction of, or irreversible alterations in, living tissue by chemical action at the site of contact. For example, a chemical is considered to be corrosive if, when tested on the intact skin of albino rabbits by the method described by the U.S. Department of Transportation in Appendix A to 49 CFR Part 173, it destroys or changes irreversibly the structure of the tissue at the site of contact following an exposure period of four hours. This term shall not refer to action on inanimate surfaces.

3. *Highly toxic*: A chemical falling within any of the following categories:

(a) A chemical that has a median lethal dose (LD₅₀) of 50 milligrams or less per kilogram of body weight when administered orally to albino rats weighing between 200 and 300 grams each.

(b) A chemical that has a median lethal dose (LD₅₀) of 200 milligrams or less per kilogram of body weight when administered by continuous contact for 24 hours (or less if death occurs within 24 hours) with the bare skin of albino rabbits weighing between two and three kilograms each.

(c) A chemical that has a median lethal concentration (LC₅₀) in air of 200 parts per million by volume or less of gas or vapor, or 2 milligrams per liter or less of mist, fume, or dust, when administered by continuous inhalation for one hour (or less if death occurs within one hour) to albino rats weighing between 200 and 300 grams each.

4. **Irritant:** A chemical, which is not corrosive, but which causes a reversible inflammatory effect on living tissue by chemical action at the site of contact. A chemical is a skin irritant if, when tested on the intact skin of albino rabbits by the methods of 16 CFR 1500.41 for four hours exposure or by other appropriate techniques, it results in an empirical score of five or more. A chemical is an eye irritant if so determined under the procedure listed in 16 CFR 1500.42 or other appropriate techniques.

5. **Sensitizer:** A chemical that causes a substantial proportion of exposed people or animals to develop an allergic reaction in normal tissue after repeated exposure to the chemical.

6. **Toxic.** A chemical falling within any of the following categories:

(a) A chemical that has a median lethal dose (LD₅₀) of more than 50 milligrams per kilogram but not more than 500 milligrams per kilogram of body weight when adminis-

tered orally to albino rats weighing between 200 and 300 grams each.

(b) A chemical that has a median lethal dose (LD₅₀) of more than 200 milligrams per kilogram but not more than 1,000 milligrams per kilogram of body weight when administered by continuous contact for 24 hours (or less if death occurs within 24 hours) with the bare skin of albino rabbits weighing between two and three kilograms each.

(c) A chemical that has a median lethal concentration (LC₅₀) in air of more than 200 parts per million but not more than 2,000 parts per million by volume of gas or vapor, or more than two milligrams per liter but not more than 20 milligrams per liter of mist, fume, or dust, when administered by continuous inhalation for one hour (or less if death occurs within one hour) to albino rats weighing between 200 and 300 grams each.

7. **Target organ effects.** The following is a target organ categorization of effects which may occur, including examples of signs and symptoms and chemicals which have been found to cause such effects. These examples are presented to illustrate the range and diversity of effects and hazards found in the workplace, and the broad scope employers must consider in this area, but are not intended to be all-inclusive.

a. Hepatotoxins:.....	Chemicals which produce liver damage.
Signs and Symptoms:	Jaundice; liver enlargement.
Chemicals:	Carbon tetrachloride; nitrosamines.
b. Nephrotoxins:.....	Chemicals which produce kidney damage.
Signs and Symptoms:	Edema; proteinuria.
Chemicals:	Halogenated hydrocarbons; uranium.
c. Neurotoxins:.....	Chemicals which produce their primary toxic effects on the nervous system.
Signs and Symptoms:	Narcosis; behavioral changes; decrease in motor functions.
Chemicals:	Mercury; carbon disulfide.
d. Agents which act on the blood or hemopoietic system:.....	Decrease hemoglobin function; deprive the body tissues of oxygen.
Signs and Symptoms:	Cyanosis; loss of consciousness.
Chemicals:	Carbon monoxide; cyanides.
e. Agents which damage the lung:	Chemicals which irritate or damage the pulmonary tissue.
Signs and Symptoms:	Cough; tightness in chest; shortness of breath.
Chemicals:	Silica; asbestos.
f. Reproductive toxins:.....	Chemicals which affect the reproductive capabilities including chromosomal damage (mutations) and effects on fetuses (teratogenesis).
Signs and Symptoms:	Birth defects; sterility.
Chemicals:	Lead; DBCP.
g. Cutaneous hazards:.....	Chemicals which affect the dermal layer of the body.
Signs and Symptoms:	Defatting of the skin; rashes; irritation.
Chemicals:	Ketones; chlorinated compounds.
h. Eye hazards:.....	Chemicals which affect the eye or visual capacity.
Signs and Symptoms:	Conjunctivitis; corneal damage.
Chemicals:	Organic solvents; acids.

APPENDIX B TO § 1900.1200—HAZARD DETERMINATION (MANDATORY)

The quality of a hazard communication program is largely dependent upon the adequacy and accuracy of the hazard determination. The hazard determination require-

ment of this standard is performance-oriented. Chemical manufacturers, importers, and employers evaluating chemicals are not required to follow any specific methods for determining hazards, but they must be able to demonstrate that they have adequately ascertained the hazards of the chemicals pro-

duced or imported in accordance with the criteria set forth in this Appendix.

Hazard evaluation is a process which relies heavily on the professional judgment of the evaluator, particularly in the area of chronic hazards. The performance-orientation of the hazard determination does diminish the duty of the chemical manufacturer, importer or employer to conduct a thorough evaluation, examining all relevant data and producing a scientifically defensible evaluation. For purposes of this standard, the following criteria shall be used in making hazard determinations that meet the requirements of this standard.

1. *Carcinogenicity:* As described in paragraph (d)(4) and Appendix A of this section, a determination by the National Toxicology Program, the International Agency for Research on Cancer, or OSHA that a chemical is a carcinogen or potential carcinogen will be considered conclusive evidence for purposes of this section.

2. *Human data:* Where available, epidemiological studies and case reports of adverse health effects shall be considered in the evaluation.

3. *Animal data:* Human evidence of health effects in exposed populations is generally not available for the majority of chemicals produced or used in the workplace. Therefore, the available results of toxicological testing in animal populations shall be used to predict the health effects that may be experienced by exposed workers. In particular, the definitions of certain acute hazards refer to specific animal testing results (see Appendix A).

4. *Adequacy and reporting of data:* The results of any studies which are designed and conducted according to established scientific principles, and which report statistically significant conclusions regarding the health effects of a chemical, shall be a sufficient basis for a hazard determination and reported on any material safety data sheet. The chemical manufacturer, importer, or employer may also report the results of other scientifically valid studies which tend to refute the findings of hazard.

APPENDIX C to § 1900.1200—INFORMATION SOURCES (ADVISORY)

The following is a list of available data sources which the chemical manufacturer, importer, or employer may wish to consult to evaluate the hazards of chemicals they produce or import:

— Any information in their own company files such as toxicity testing results or illness experience of company employees.

— Any information obtained from the supplier of the chemical, such as material safety data sheets or product safety bulletins.

— Any pertinent information obtained from the following source list (latest editions should be used):

Condensed Chemical Dictionary

Van Nostrand Reinhold Co., 135 West 50th Street, New York, NY 10020

The Merck Index: An Encyclopedia of Chemicals and Drugs

Merck and Company, Inc., 126 E. Lincoln Avenue, Rahway, NJ 07065

IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man

Geneva: World Health Organization, International Agency for Research on Cancer, 1972-1977. (Multivolume work), 49 Sheridan Street, Albany, New York

Industrial Hygiene and Toxicology, by F. A. Patty

John Wiley & Sons, Inc., New York, NY (Five volumes)

Clinical Toxicology of Commercial Products

Gleason, Gosselin and Hodge

Casarett and Doull's Toxicology: The Basic Science of Poisons

Doull, Klaassen, and Amdur, Macmillan Publishing Co., Inc., New York, NY

Industrial Toxicology, by Alice Hamilton and Harriet L. Hardy

Publishing Sciences Group, Inc., Acton, MA

Toxicology of the Eye, by W. Morton Grant

Charles C. Thomas, 301-327 East Lawrence Avenue, Springfield, IL

Recognition of Health Hazards in Industry

William A. Burgess, John Wiley and Sons, 605 Third Avenue, New York, NY 10158

Chemical Hazards of the Workplace

Nick H. Proctor and James P. Hughes, J. P. Lipincott Company, 6 Winchester Terrace, New York, NY 10022

Handbook of Chemistry and Physics

Chemical Rubber Company, 18901 Cranwood Parkway, Cleveland, OH 44128

Threshold Limit Values for Chemical Substances and Physical Agents in the Workroom Environment with Intended Changes

American Conference of Governmental Industrial Hygienists, 6500 Glenway Avenue, Bldg. D-5, Cincinnati, OH 45211

NOTE: The following documents are on sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Occupational Health Guidelines

NIOSH/OSHA (NIOSH Pub. No. 81-123)

NIOSH/OSHA Pocket Guide to Chemical Hazards

NIOSH Pub. No. 78-210

Registry of Toxic Effects of Chemical Substances

U.S. Department of Health and Human Services, Public Health Service, Center for Disease Control, National Institute

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for Occupational Safety and Health
(NIOSH Pub. No. 80-102)

The Industrial Environment—Its Evaluation and Control

U.S. Department of Health and Human Services, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health (NIOSH Pub. No. 74-117)

Miscellaneous Documents—National Institute for Occupational Safety and Health

1. Criteria for a recommended standard
* * * Occupational Exposure to "—"
2. Special Hazard Reviews
3. Occupational Hazard Assessment
4. Current Intelligence Bulletins

BIBLIOGRAPHIC DATA BASES

Service Provider and File Name

Bibliographic Retrieval Services (BRS), Corporation Park, Bldg. 702, Scotia, New York 12302

AGRICOLA
BIOSIS PREVIEWS
CA CONDENSATES
CA SEARCH
DRUG INFORMATION
MEDLARS
MEDOC
NTIS
POLLUTION ABSTRACTS
SCIENCE CITATION INDEX
SSIE

Lockheed—DIALOG, Lockheed Missiles & Space Company, Inc., P.O. Box 44481, San Francisco, CA 94144

AGRICOLA
BIOSIS PREV. 1972-PRESENT
BIOSIS PREV. 1969-71
CA CONDENSATES 1970-71
CA SEARCH 1972-76
CA SEARCH 1977-PRESENT
CHEMNAME
CONFERENCE PAPERS INDEX
FOOD SCIENCE & TECH. ABSTR.
FOODS ADLIBRA
INTL. PHARMACEUTICAL ABSTR.
NTIS
POLLUTION ABSTRACTS
SCISEARCH 1978-PRESENT
SCISEARCH 1974-77
SSIE CURRENT RESEARCH

SDC—ORBIT, SDC Search Service, Department No. 2230, Pasadena, CA 91051

AGRICOLA
BIOCODES
BIOSIS/BIO6973
CAS6771/CAS7276
CAS77
CHEMDEX
CONFERENCE
ENVIROLINE
LABORDOC
NTIS
POLLUTION
SSIE

29 CFR Ch. XVII (7-1-86 Edition)

Chemical Information System (CIS), Chemical Information Systems Inc., 7215 Yorke Road, Baltimore, MD 21212

Structure & Nomenclature Search System
Acute Toxicity (RTECS)

Clinical Toxicology of Commercial Products

Oil and Hazardous Materials Technical Assistance Data System

National Library of Medicine, Department of Health and Human Services, Public Health Service, National Institutes of Health, Bethesda, MD 20209

Toxicology Data Bank (TDB)

MEDLIN

TOXLINE

CANCERLIT

RTECS

APPENDIX D TO § 1910.1200—DEFINITION OF "TRADE SECRET" (MANDATORY)

The following is a reprint of the *Restatement of Torts* section 757, comment b (1939):

b. Definition of trade secret. A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers. It differs from other secret information in a business (see § 759 of the *Restatement of Torts* which is not included in this Appendix) in that it is not simply information as to single or ephemeral events in the conduct of the business, as, for example, the amount or other terms of a secret bid for a contract or the salary of certain employees, or the security investments made or contemplated, or the date fixed for the announcement of a new policy or for bringing out a new model or the like. A trade secret is a process or device for continuous use in the operations of the business. Generally it relates to the production of goods, as, for example, a machine or formula for the production of an article. It may, however, relate to the sale of goods or to other operations in the business, such as a code for determining discounts, rebates or other concessions in a price list or catalogue, or a list of specialized customers, or a method of

bookkeeping or other office management.

Secrecy. The subject matter of a trade secret must be secret. Matters of public knowledge or of general knowledge in an industry cannot be appropriated by one as his secret. Matters which are completely disclosed by the goods which one markets cannot be his secret. Substantially, a trade secret is known only in the particular business in which it is used. It is not requisite that only the proprietor of the business know it. He may, without losing his protection, communicate it to employees involved in its use. He may likewise communicate it to others pledged to secrecy. Others may also know of it independently, as, for example, when they have discovered the process or formula by independent invention and are keeping it secret. Nevertheless, a substantial element of secrecy must exist, so that, except by the use of improper means, there would be difficulty in acquiring the information. An exact definition of a trade secret is not possible. Some factors to be considered in determining whether given information is one's trade secret are: (1) The extent to which the information is known outside of his business; (2) the extent to which it is known by employees and others involved in his business; (3) the extent of measures taken by him to guard the secrecy of the information; (4) the value of the information to him and his competitors; (5) the amount of effort or money expended by him in developing the information; (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

Novelty and prior art. A trade secret may be a device or process which is patentable; but it need not be that. It may be a device or process which is clearly anticipated in the prior art or one which is merely a mechanical improvement that a good mechanic can make. Novelty and invention are not requisite for a trade secret as they are for patentability. These requirements are essential to patentability because a patent protects against unlicensed use of the patented device or process even by one who discovers it properly through independent research. The

patent monopoly is a reward to the inventor. But such is not the case with a trade secret. Its protection is not based on a policy of rewarding or otherwise encouraging the development of secret processes or devices. The protection is merely against breach of faith and reprehensible means of learning another's secret. For this limited protection it is not appropriate to require also the kind of novelty and invention which is a requisite of patentability. The nature of the secret is, however, an important factor in determining the kind of relief that is appropriate against one who is subject to liability under the rule stated in this Section. Thus, if the secret consists of a device or process which is a novel invention, one who acquires the secret wrongfully is ordinarily enjoined from further use of it and is required to account for the profits derived from his past use. If, on the other hand, the secret consists of mechanical improvements that a good mechanic can make without resort to the secret, the wrongdoer's liability may be limited to damages, and an injunction against future use of the improvements made with the aid of the secret may be inappropriate.

Information not a trade secret. Although given information is not a trade secret, one who receives the information in a confidential relation or discovers it by improper means may be under some duty not to disclose or use that information. Because of the confidential relation or the impropriety of the means of discovery, he may be compelled to go to other sources for the information. As stated in Comment *a*, even the rule stated in this Section rests not upon a view of trade secrets as physical objects of property but rather upon abuse of confidence or impropriety in learning the secret. Such abuse or impropriety may exist also where the information is not a trade secret and may be equally a basis for liability. The rules relating to the liability for duties arising from confidential relationships generally are not within the scope of the Restatement of this Subject. As to the use of improper means to acquire information, see § 759.

§ 1910.1499

[48 FR 53340, Nov. 25, 1983, as amended at 50 FR 48758, Nov. 27, 1985]

§ 1910.1499 Source of standards.

Section 1910.1000.....	41 CFR 50-204.50, except for Table Z-2, the source of which is American National Standards Institute, Z37 series.
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[40 FR 23073, May 28, 1975]

§ 1910.1500 Standards organizations.

Specific standards of the following organizations have been referred to in

29 CFR Ch. XVII (7-1-86 Edition)

this subpart. Copies of the standards may be obtained from the issuing organization.

American Conference of Governmental
Industrial Hygienists
1014 Broadway
Cincinnati, Ohio 45202
American National Standards Institute
1430 Broadway
New York, New York 10018

[40 FR 23073, May 28, 1975, as amended at 43 FR 57603, Dec. 8, 1978]