

ADDENDUM E

**TITLE 8,
CALIFORNIA
ADMINISTRATIVE
CODE SECTION
5194**

§5194. Hazard Communication.

(a) (Reserved)

(b) Scope and Application.

(1) This section requires manufacturers or importers to assess the hazards of substances which they produce or import, and all employers to provide information to their employees about the hazardous substances to which they may be 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.

(2) This section applies to any hazardous substance which is known to be present in the work place in such a manner that employees may be exposed under normal conditions of use or in a reasonably foreseeable emergency resulting from work place operations.

(3) This section applies to laboratories that primarily provide quality control analyses for manufacturing processes or that produce hazardous substances for commercial purposes, and to all other laboratories except those under the direct supervision and regular observation of an individual who has knowledge of the physical hazards, health hazards, and emergency procedures associated with the use of the particular hazardous substances involved, and who conveys this knowledge to employees in terms of safe work practices. Such excepted laboratories must also ensure that labels of incoming containers of hazardous substances are not removed or defaced pursuant to section 5194(f)(4), and must maintain any material safety data sheets that are received with incoming shipments of hazardous substances and ensure that they are readily available to laboratory employees pursuant to section 5194(g).

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

(A) 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;

(B) Any food, food additive, color additive, drug, cosmetic, or medical or veterinary device, 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;

(C) 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;

(D) 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:

(A) 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 (42U.S.C. 6901 et seq.), when subject to regulations issued under that Act by the Environmental Protection Agency;

(B) Tobacco or tobacco products;

(C) Wood or wood products including lumber which will not be processed, where the manufacturer or importer can establish that the only hazard they pose to employees is the potential for flammability or combustibility (non-excluded hazardous substances which are used in conjunction with wood or wood products, or are known to be present as impurities in those materials, and wood which may be subsequently sawed or cut, generating dust, are covered by this section);

(D) Articles (hazardous substances used in the manufacture or use of an article are covered by this section unless otherwise excluded);

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

(F) Retail food sale establishments and all other retail trade establishments, exclusive of processing and repair work areas;

(G) Consumer products packaged for distribution to, and use by, the general public, provided that employee exposure to the product is not significantly greater than the consumer exposure occurring during the principal consumer use of the product;

(H) The use of a substance in compliance with regulations of the Director of the Department of Pesticide Regulation issued pursuant to section 12981 of the Food and Agricultural Code.

(I) Work operations where employees only handle substances in sealed containers which are not opened under normal conditions of use (such as are found in marine cargo handling, warehousing, or transportation); however, this section does apply to these operations as follows:

1. Employers shall ensure that labels on incoming containers of hazardous substances are not removed or defaced;

2. Employers shall maintain copies of any material safety data sheets that are received with incoming shipments of the sealed containers of hazardous substances, shall obtain a material safety data sheet for sealed containers of hazardous substances received without a material safety data sheet if an employee requests the material safety data sheet, and shall ensure that the material safety data sheets are readily accessible during each work shift to employees when they are in their work area(s); and,

3. Employers shall ensure that employees are provided with information and training in accordance with subsection (h) except for the location and availability of the written hazard communication program under subsection (h)(2)(C), to the extent necessary to protect them in the event of a spill or leak of a hazardous substance from a sealed container.

(6) Proposition 65 Warnings.

(A) Notwithstanding any other provision of law including the preceding subsections, an employer which is a person in the course of doing business within the meaning of Health and Safety Code Section 25249.11(a) and

(b), is subject to the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65 or the “Act”) (Health and Safety Code § 25249.5 et seq.), and shall comply with the Act in the manner set forth in subsections (B) and (C) below. The following employers are not subject to the Act:

1. an employer employing fewer than ten employees;
2. any city, county, or district or any department or agency thereof or the state or any department or agency thereof or the federal government or any department or agency thereof;
3. any entity in its operation of a public water system as defined in Health and Safety Code Section 4010.1.

(B) Exposures Subject to Proposition 65 and Hazard Communication. Before exposing any employee to any hazardous substance that otherwise falls within the scope of this section and which requires a warning under this Act (see 22 CCR Section 12000, Chemicals Known to the State to Cause Cancer or Reproductive Toxicity) except as provided in subsection (D) below, any employer subject to the Act shall comply with the requirements set forth in subsections (d) through (k). Such compliance shall be deemed compliance with the Act.

(C) Exposures Subject to Proposition 65 Only. Before knowingly and intentionally exposing any employee to any hazardous substance that does not otherwise fall within the scope of the section, but which requires a warning under the Act (see 22 CCR Section 12000, Chemicals Known to the State to Cause Cancer or Reproductive Toxicity) except as provided in subsection (D) below, any employer subject to the Act shall either provide a warning to employees in compliance with California Code of Regulations Title 22 (22 CCR) Section 12601(c) in effect on May 9, 1991 or shall comply with the requirements set forth in subsections (d) through (k).

(D) Exposures Not Subject to Proposition 65. A warning required by subsection (B) and (C) above shall not apply to any of the following:

1. An exposure for which federal law governs warning in a manner that preempts state authority.
2. An exposure that takes place less than twelve months subsequent to the listing of the chemical in 22 CCR Section 12000.
3. An exposure for which the employer responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for the chemicals known to the State to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1,000) times the level in question for chemicals known to the State to cause reproductive toxicity, based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical in 22 CCR Section 12000. In any enforcement action the burden of showing that an exposure meets the criteria of this subsection shall be on the employer.

(E) Additional Enforcement of Proposition 65. In addition to any other applicable enforcement provision, violations or threatened violations of the Act may be enforced in the manner set forth in Health and Safety Code Section 25249.7 for violations and threatened violations of Health and Safety Code Section 25249.6. Compliance with 22 CCR Section 12601(c) in effect on May 9, 1991 shall be deemed a defense to an enforcement action under Health and Safety Code Section 25249.7.

(F) All terms and provisions of subsection (b)(6) shall have the same meaning as the following 22 CCR Sections in effect on May 9, 1991: 12201(a), 12201(b), 12201(c), 12201(d), 12201(f), 12201(k), 12502, 12601, 12701(a), 12701(b), 12701(d), 12703, 12705, 12707, 12709, 12711, 12721, 12801, 12803, 12805, 12821 and 12901. The above listed 22 CCR Sections in effect on May 9, 1991 are printed in Appendix E to this section.

Additionally, all terms and provisions of subsection (b)(6) shall have the same meaning as in the Act and in 22 CCR Section 12000.

(c) Definitions.

Article.

A manufactured item: (1) Which is formed to a specific shape or design during manufacture; (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (3) which does not release, or otherwise result in exposure to, a hazardous substance under normal conditions of use or in a reasonably foreseeable emergency resulting from workplace operations.

CAS number.

The unique identification number assigned by the Chemical Abstracts Service to specific chemical substances.

Chemical name.

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 substance for the purpose of conducting a hazard evaluation.

Chief.

The Chief of the Division of Occupational Safety and Health, P.O. Box 420603, San Francisco, CA 94142, or designee.

Combustible liquid.

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.

Any designation or identification such as code name, code number, trade name, brand name or generic name used to identify a substance other than by its chemical name.

Compressed gas.

Compressed gas means:

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

(B) 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

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

Container.

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

Department.

The Department of Industrial Relations, P.O. Box 420603, San Francisco, CA 94142, or designee.

Designated representative.

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.

The Director of Industrial Relations, P.O. Box 420603, San Francisco, CA 94142, or designee.

Distributor.

A business, other than a manufacturer or importer, which supplies hazardous substances to other distributors or to employers.

Division.

The Division of Occupational Safety and Health (Cal/OSHA), California Department of Industrial Relations, or designee.

Emergency.

Any potential occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment, which may or does result in a release of a hazardous substance into the workplace.

Employee.

Every person who is required or directed by any employer, to engage in any employment, or to go to work or be at any time in any place of employment.

Employer.

Employer means:

- (A) The State and every State agency.
- (B) Each county, city, district, and all public and quasi-public corporations and public agencies therein.
- (C) Every person including any public service corporation, which has any natural person in service.
- (D) The legal representative of any deceased employer.

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

Exposure or Exposed.

Any situation arising from work operation where an employee may ingest, inhale, absorb through the skin or eyes, or otherwise come into contact with a hazardous substance.

Flammable.

A substance that falls into one of the following categories:

(A) Aerosol, flammable. 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;

(B) Gas, flammable:

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

2. 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;

(C) Liquid, flammable. 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.

(D) Solid, flammable. A solid, other than a blasting agent or explosive as defined in section 5237(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.

The minimum temperature at which a liquid gives off a vapor in sufficient concentration to ignite when tested as follows:

(A) 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 have a tendency to form a surface film under test; or

(B) 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 have a tendency to form a surface film under test; or

(C) 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.

Hazard warning.

Any words, pictures, symbols, or combination thereof appearing on a label or other appropriate form of warning which convey the health hazards and physical hazards of the substance(s) in the container(s).

Hazardous substance.

Any substance which is a physical hazard or a health hazard or is included in the List of Hazardous Substances prepared by the Director pursuant to Labor Code section 6382.

Health hazard.

A substance 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 substances 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 substance is to be considered hazardous for purposes of this standard.

Identity.

Any chemical or common name which is indicated on the material safety data sheet (MSDS) for the substance. The identity used shall permit crossreferences to be made among the required list of hazardous substances, the label and the MSDS.

Immediate use.

The hazardous substance 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.

The first business with employees within the Customs Territory of the United States which receives hazardous substances produced in other countries for the purpose of supplying them to distributors or purchasers within the United States.

Label.

Any written, printed, or graphic material displayed on or affixed to containers of hazardous substances.

Manufacturer.

A person who produces, synthesizes, extracts, or otherwise makes a hazardous substance.

Material safety data sheet (MSDS). Written or printed material concerning a hazardous substance which is prepared in accordance with section 5194(g).

Mixture.

Any solution or intimate admixture of two or more substances, at least one of which is present as a hazardous substance, which do not react chemically with each other.

NIOSH. The National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services.

Organic peroxide.

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.

A substance other than a blasting agent or explosive as defined in section 5237(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.

A substance 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.

To manufacture, process, formulate, repackage, or relabel.

Pyrophoric.

A substance that will ignite spontaneously in air at a temperature of 130° F (54.4° C) or below.

Responsible party.

Someone who can provide additional information on the hazardous substance and appropriate emergency procedures, if necessary.

Specific chemical identity.

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

Substance.

Any element, chemical compound or mixture of elements and/or compounds.

Trade secret.

Any confidential formula, pattern, process, device, information, or compilation of information which gives its user an opportunity to obtain a business advantage over competitors who do not know or use it. A trade secret

shall not include chemical identity information which is readily discoverable through qualitative analysis. Appendix D sets out the criteria to be used in evaluating trade secrets.

Unstable (reactive).

A substance 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.

To package, handle, react, or transfer.

Water-reactive.

A substance that reacts with water to release a gas that is either flammable or presents a health hazard.

Work area.

A room or defined space in a workplace where hazardous substances are produced or used, and where employees are present.

Workplace.

Any place, and the premises appurtenant thereto, where employment is carried on, except a place the health and safety jurisdiction over which is vested by law in, and actively exercised by, any state or federal agency other than the Division.

(d) Hazard Determination.

(1) Manufacturers and importers shall evaluate substances produced in their workplaces or imported by them to determine if they are hazardous. Employers are not required to evaluate substances unless they choose not to rely on the evaluation performed by the manufacturer or importer for the substance to satisfy this requirement.

(2) Manufacturers, importers, or employers evaluating substances 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 manufacturer, importer, or employer evaluating substances shall treat any of the following sources as establishing that the substances listed in them are hazardous:

(A) The list of hazardous substances prepared by the Director pursuant to Labor Code section 6382 and as promulgated in title 8, California Code of Regulations, section 339. The concentrations and footnotes which are applicable to the list shall be understood to modify the same substance on all other source lists or hazard determinations set forth in sections 5194(d)(3)(B)-5194(d)(5)(D).

(B) 29 CFR part 1910, subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration (OSHA).

(C) Threshold Limit Values for Chemical Substances in the Work Environment, American Conference of Governmental Industrial Hygienists (ACGIH) (latest edition).

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

(4) Manufacturers, importers, and employers evaluating substances shall treat any of the following sources as establishing that a substance is a carcinogen or potential carcinogen for hazard communication purposes:

(A) National Toxicology Program (NTP), Annual Report on Carcinogens, (latest edition).

(B) International Agency for Research on Cancer (IARC) Monographs (latest editions).

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

Note to (d)(4): The Registry of Toxic Effects of Chemical Substances published by the National Institute for Occupational Safety and Health indicates whether a substance has been found by NTP or IARC to be a potential carcinogen.

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

(A) 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;

(B) 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 section 5194(d)(4);

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

(D) If the manufacturer, importer, or 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 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) Manufacturers, importers, or employers evaluating hazardous substances shall describe in writing the procedures they use to determine the hazards of the substance they evaluate. The written procedures are to be made available, upon request, to employees, their designated representatives, the Director, and NIOSH. The written description may be incorporated into the written hazard communication program required under section 5194(e).

(e) Written Hazard Communication Program.

(1) Employers shall develop, implement, and maintain at the workplace a written hazard communication program for their employees which at least describes how the criteria specified in sections 5194(f), (g), and (h)

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:

(A) A list of the hazardous substances 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);

(B) 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 substances contained in unlabeled pipes in their work areas.

(2) In multi-employer workplaces, the written hazard communication program shall include the methods employers will use to inform any employers sharing the same work area of the hazardous substances to which their employees may be exposed while performing their work, and any suggestions for appropriate protective measures, including the following:

(A) The methods the employer will use to provide the other employer(s) with access to the material safety data sheet, or to make it available at a central location in the workplace, for each hazardous substance the other employer(s)' employees may be exposed to while working;

(B) The methods the employer will use to inform the other employer(s) of any precautionary measures that need to be taken to protect employees during the workplace's normal operating conditions and in foreseeable emergencies; and,

(C) The methods the employer will use to inform the other employer(s) of the labeling system used in the workplace.

(3) The employer shall make the written hazard communication program available, upon request, to employees, their designated representatives, the Chief, and NIOSH, in accordance with the requirements of section 3204(e).

(f) Labels and Other Forms of Warning.

(1) The manufacturer, importer, or distributor shall ensure that each container of hazardous substances leaving the workplace is labeled, tagged or marked with the following information:

(A) Identity of the hazardous substance(s);

(B) Appropriate hazard warnings; and

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

Exception to (f)(1): For solid metal (such as a steel beam or a metal casting) that is not exempted as an article due to its downstream use, the required label may be transmitted to the customer at the time of the initial shipment, and need not be included with subsequent shipments to the same employer unless the information on the label changes. The label may be transmitted with the initial shipment itself, or with the material safety data sheet that is to be provided prior to or at the time of the first shipment. This exception to requiring labels on every container of hazardous substances is only for the solid metal itself and does not apply to hazardous substances used in conjunction with, or known to be present with, the metal and to which the employees handling the metal may be exposed (for example, cutting fluids or lubricants).

(2) Manufacturers, importers, or distributors shall ensure that each container of hazardous substances 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 substance is regulated by these orders in a substance-specific health standard, the 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 sections 5194(f)(5) and (f)(6) the employer shall ensure that each container of hazardous substances in the workplace is labeled, tagged, or marked with the following information:

(A) Identity of the hazardous substance(s) contained therein; and

(B) 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 section 5194(f)(4) to be on a label. The written materials shall be readily accessible to the employees in their work area throughout each work shift. In construction, the employer may use such written materials in lieu of affixing labels to individual containers as long as the alternative method identifies and accompanies the containers to which it is applicable and conveys the information required to be on a label.

(6) The employer is not required to label portable containers into which hazardous substances are transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer. In construction, the employer is not required to label portable containers into which hazardous substances are transferred from labeled containers, so long as either the labeled container stays on the jobsite or the employer has complied with section 5194(f)(5).

(7) The employer shall not remove or intentionally deface existing labels on incoming containers of hazardous substances, 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 manufacturer, importer, distributor, or employer need not affix new labels to comply with this section if existing labels already convey the required information.

(10) Manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a substance shall revise the labels for the substance within three months of becoming aware of the new information. Labels on containers of hazardous substances shipped after that time shall contain the new information. If the substance is not currently produced or imported, the manufacturer, importer, distributor, or employer shall add the information to the label before the substance is shipped or introduced into the workplace again.

(g) Material Safety Data Sheets.

(1) Manufacturers and importers shall obtain or develop a material safety data sheet for each hazardous substance they produce or import. Employers shall have a material safety data sheet for each hazardous substance which they use.

Note to (g)(1): Employers should also refer to section 3204 concerning information to be retained after a particular substance is no longer in use.

(2) Each material safety data sheet shall be in English (although the employer may maintain copies in other languages as well) and shall contain at least the following information:

(A) The identity used on the label, and, except as provided for in section 5194(i) on trade secrets:

1. If the hazardous substance is a single substance, its chemical and common name(s) and CAS number(s);
2. If the hazardous substance is a mixture which has been tested as a whole to determine its hazards, the chemical, common name(s), and CAS number(s) of the ingredients which contribute to these known hazards, and the common name(s) of the mixture itself; or,
3. If the hazardous substance is a mixture which has not been tested as a whole:

a. The chemical and common name(s), and CAS number(s) of all ingredients which have been determined to be health hazards, and which comprise 1% or greater of the composition, except that substances identified as carcinogens under subsection 5194(d)(4) shall be listed if the concentrations are 0.1% or greater;

b. The chemical and common name(s), and CAS number(s) of all ingredients which comprise less than 1% (0.1% for carcinogens) of the mixture, if there is evidence that the ingredient(s) could be released from the mixture in concentrations which would exceed an established OSHA permissible exposure limit or ACGIH Threshold Limit Value, or could present a health hazard to employees; and,

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

(B) Physical and chemical properties of the hazardous substance (such as vapor pressure, flash point);

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

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

(E) The potential route(s) of entry;

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

(G) Whether the hazardous substance 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;

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

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

(J) Emergency and first-aid procedures;

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

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

(M) A description in lay terms, if not otherwise provided, on either a separate sheet or with the body of the information specified in this section, of the specific potential health risks posed by the hazardous substance intended to alert any person reading the information.

(3) If no relevant information is found for any given category on the material safety data sheet, the manufacturer, importer, or employer preparing the material safety data sheet shall mark it to indicate that no information was found. If the category is not applicable to the hazardous substance involved, the space shall be marked to indicate that.

(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 manufacturer, importer or employer may prepare one material safety data sheet to apply to all of these similar mixtures.

(5) The 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 manufacturer, importer, or employer become aware of any significant information regarding the hazards of a substance, or ways to protect against the hazards, this new information shall be added to the material safety data sheet within three months. If the substance is not currently being produced or imported, the manufacturer or importer shall add the information to the material safety data sheet before the substance is introduced into the workplace again.

(6) Manufacturers or importers shall ensure that distributors and purchasers of hazardous substances 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 manufacturer or importer shall either provide material safety data sheets with the shipped containers or send them to the purchaser prior to or at the time of the shipment. If the material safety data sheet is not provided with the shipment, the purchaser shall obtain one from the manufacturer, importer, or distributor as soon as possible. The manufacturer or importer shall also provide distributors or employers with a material safety data sheet upon request.

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

(8) The employer shall maintain copies of the required material safety data sheets for each hazardous substance 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). (Electronic access, microfiche, and other alternatives to maintaining paper copies of the material safety data sheets are permitted as long as no barriers to immediate employee access in each workplace are created by such options.)

(9) Where employees must travel between workplaces during a workshift, i.e., their work is carried out at more than one geographical location, the material safety data sheets may be kept at a central location at the primary workplace facility. In this situation, the employer shall ensure that employees can immediately obtain the required information in an emergency.

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

(11) Material safety data sheets shall also be made readily available, upon request, to designated representatives, and to the Chief, in accordance with the requirements of section 3204(e). NIOSH and the employee's physician shall also be given access to material safety data sheets in the same manner.

(12) If the material safety data sheet, or any item of information required by section 5194(g)(2), is not provided by the manufacturer or importer, the employer shall:

(A) Within 7 working days of noting this missing information, either from a request or in attempting to comply with section 5194(g)(1), make written inquiry to the manufacturer or importer of a hazardous substance responsible for the material safety data sheet, asking that the complete material safety data sheet be sent to the employer. If the employer has made written inquiry in the preceding 12 months as to whether the substance or product is subject to the requirements of the Act or the employer has made written inquiry within the last 6 months requesting new, revised or later information on the material safety data sheet for the hazardous substance, the employer need not make additional written inquiry.

(B) Notify the requester in writing of the date that the inquiry was made, to whom it was made, and the response, if any, received. Providing the requestor with a copy of the inquiry sent to the manufacturer, producer or seller and a copy of the response will satisfy this requirement.

(C) Notify the requestor of the availability of the material safety data sheet within 15 days of the receipt of the material safety data sheet from the manufacturer, producer or seller or provide a copy of the material safety data sheet to the requestor within 15 days of the receipt of the material safety data sheet from the manufacturer, producer or seller.

(D) Send the Director a copy of the written inquiry if a response has not been received within 25 working days.

(13) The preparer of a material safety data sheet shall provide the Director with a copy of the material safety data sheet. Where a trade secret claim is made, the preparer shall submit the information specified in section 5194(i)(15).

(h) Employee Information and Training.

(1) Employers shall provide employees with effective information and training on hazardous substances in their work area at the time of their initial assignment, and whenever a new hazard is introduced into their work area. Information and training may relate to general classes of hazardous substances to the extent appropriate and related to reasonably foreseeable exposures of the job.

(2) Information and training shall consist of at least the following topics:

(A) Employees shall be informed of the requirements of this section.

(B) Employees shall be informed of any operations in their work area where hazardous substances are present.

(C) Employees shall be informed of the location and availability of the written hazard communication program, including the list(s) of hazardous substances and material safety data sheets required by this section.

(D) Employees shall be trained in the methods and observations that may be used to detect the presence or release of a hazardous substance in the work area (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous substances when being released, etc.).

(E) Employees shall be trained in the physical and health hazards of the substances in the work area, and the measures they can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous substances, such as appropriate work practices, emergency procedures, and personal protective equipment to be used.

(F) Employees shall be trained in 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.

(G) Employers shall inform employees of the right:

1. To personally receive information regarding hazardous substances to which they may be exposed, according to the provisions of this section;
2. For their physician or collective bargaining agent to receive information regarding hazardous substances to which the employee may be exposed according to provisions of this section;
3. Against discharge or other discrimination due to the employee's exercise of the rights afforded pursuant to the provisions of the Hazardous Substances Information and Training Act.

(3) Whenever the employer receives a new or revised material safety data sheet, such information shall be provided to employees on a timely basis not to exceed 30 days after receipt, if the new information indicates significantly increased risks to, or measures necessary to protect, employee health as compared to those stated on a material safety data sheet previously provided.

(i) Trade Secrets.

(1) The manufacturer, importer or employer may withhold the specific chemical identity of a hazardous substance from the material safety data sheet, provided that:

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

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

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

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

(2) Where a physician or nurse determines that a medical emergency exists and the specific chemical identity of a hazardous substance is necessary for emergency or first-aid treatment, the manufacturer, importer, or employer shall immediately disclose the specific chemical identity of a trade secret substance to that physician or nurse, regardless of the existence of a written statement of need or a confidentiality agreement. The manufacturer, importer, or employer may require a written statement of need and confidentiality agreement, in accordance with the provisions of sections 5194(i)(3) and (4), as soon as circumstances permit.

(3) In non-emergency situations, a manufacturer, importer, or employer shall, upon request, disclose a specific chemical identity, otherwise permitted to be withheld under section 5194(i)(1), to a health or safety professional (i.e., physician, nurse, industrial hygienist, safety professional, toxicologist, or epidemiologist) providing medical or other occupational health services to exposed employee(s), and to employees and designated representatives, if:

(A) The request is in writing;

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

1. To assess the hazards of the substances to which employees will be exposed;
2. To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels;
3. To conduct pre-assignment or periodic medical surveillance of exposed employees;
4. To provide medical treatment to exposed employees;
5. To select or assess appropriate personal protective equipment for exposed employees;
6. To design or assess engineering controls or other protective measures for exposed employees; and,
7. To conduct studies to determine the health effects of exposure.

(C) 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 or safety professional, employee or designated representative to provide the occupational health services described in section 5194(i)(3)(B):

1. The properties and effects of the substance;
2. Measures for controlling workers' exposure to the substance;
3. Methods of monitoring and analyzing worker exposure to the substance; and,
4. Methods of diagnosing and treating harmful exposures to the substance;

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

(E) The health or safety professional, employee, or designated representative and the employer or contractor of the health or safety professional's services (i.e., downstream employer, labor organization, or individual employee), agree in a written confidentiality agreement that the health or safety 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 the Director, as provided in section 5194(i)(6), except as authorized by the terms of the agreement or by the manufacturer, importer, or employer.

(4) The confidentiality agreement authorized by section 5194(i)(3)(D) shall 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 or safety professional, employee, or designated representative receiving the trade secret information decides that there is a need to disclose it to the Director, then the manufacturer, importer, or employer who provided the information shall be informed by the health or safety professional, employee, or designated representative prior to, or at the same time as, such disclosure.

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

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

(B) Be in writing;

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

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

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

(8) The health or safety professional, employee, or designated representative whose request for information is denied under section 5194(i)(3) may refer the request and the written denial of the request to the Director for consideration.

(9) When a health or safety professional, employee, or designated representative refers the denial to the Director under section 5194(i)(8), or upon the Director's own initiative when receiving information pursuant to section 5194(g)(13) which is claimed to be a trade secret, the Director shall consider the evidence to determine if:

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

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

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

(10) If the Director determines that the specific chemical identity requested under section 5194(i)(3) is not a bona fide trade secret, or that it is a trade secret but the requesting health or safety 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 manufacturer, importer, or employer will be subject to citation by the Director. The Director shall so notify the manufacturer, importer, or employer by certified mail.

(11) The manufacturer, importer, or employer shall have 15 days after receipt of notification under section 5194(i)(10) to provide the Director with a complete justification and statement of the grounds on which the trade secret privilege is claimed. This justification and statement shall be submitted by certified mail.

(12) The Director shall determine whether such information is protected as a trade secret within 15 days after receipt of the justification and statement required by section 5194(i)(11), or if no justification and statement is filed, within 30 days of the original notice, and shall notify the employer or manufacturer and any party who has requested the information pursuant to the California Public Records Act of that determination by certified mail. If the Director determines that the information is not protected as a trade secret, the final notice shall also specify a date, not sooner than 15 days after the date of mailing of the final notice, when the information shall be available to the public.

(13) Prior to the date specified in the final notice provided pursuant to section 5194(i)(12), a manufacturer, importer, or employer may institute an action in an appropriate superior court for a declaratory judgment as to whether such information is subject to protection from disclosure.

(14) If a manufacturer, importer, or employer demonstrates to the Director that the execution of a confidentiality agreement as provided for by section 5194(i)(10) would not provide sufficient protection against the potential harm from the unauthorized disclosure of a trade secret specific chemical identity, the Director may issue such orders to impose such additional limitations or conditions upon the disclosure of the requested information as may be appropriate to assure that the occupational health services are provided without an undue risk of harm to the manufacturer, importer, or employer.

(15) Notwithstanding the existence of a trade secret claim, a manufacturer, importer, or employer shall disclose to the Director the specific chemical identity of any hazardous substance in a product for which trade secrecy is claimed. Where there is a trade secret claim, such claim shall be made no later than at the time the information is provided to the Director so that suitable determinations of trade secret status can be made and the necessary protections can be implemented.

(16) Nothing in section 5194(i) shall be construed as requiring the disclosure under any circumstances of process or percentage of mixture information which is a trade secret.

(j) Appendices.

(1) Appendices A, B, and D to this section are incorporated as part of this section and the provisions are mandatory.

(2) Appendix C contains information which is not intended to create any additional obligations not otherwise imposed or to detract from any existing obligation.

(3) Appendix E contains the following 22 CCR Sections: 12201(a), 12201(b), 12201(c), 12201(d), 12201(f), 12201(k), 12502, 12601, 12701(a), 12701(b), 12701(d), 12703, 12705, 12707, 12709, 12711, 12721, 12801, 12803, 12805, 12821, and 12901 in effect on May 9, 1991 that are referred to in subsection (b)(6).

NOTE

Authority cited: Sections 50.7, 142.3 and 6398, Labor Code. Reference: Sections 50.7, 142.3 and 6361-6399.7, Labor Code; Sections 25249.6, 25249.7, 25249.8, 25249.10, 25249.11, 25249.12 and 25249.13, Health and Safety Code; California Lab. Federation v. Occupational Safety and Health Stds. Bd. (1990) 221 Cal.App.3d 1547 [271 Cal. Rptr. 310]; and United Steelworkers of America v. Auchter (3d Cir. 1985) 763 F.2d 728.

HISTORY

1. New section filed 12-9-81; designated effective 180 days following adoption of a list of hazardous substances pursuant to the Act by the Director, Department of Industrial Relations (Register 81, No. 50).
2. Repealer and new section (including appendices A-C) filed 11-22-85; designated effective 11-25-85 pursuant to Government Code section 11346.2(d) (Register 85, No. 47).
3. Order of Repeal of subsection (a) pursuant to Government Code section 11342(b), amendment, and new appendix D filed 5-26-87; operative 6-25-87 (Register 87, No. 23).
4. Change without regulatory effect removing chapter heading filed 3-6-91; operative 4-4-91 (Register 91, No. 15).
5. Change without regulatory effect repealing Article 110 heading “Special Hazardous Substances and Processes” filed 3-6-91 pursuant to section 100, title 1, California Code of Regulations (Register 91, No. 15).
6. New subsections (b)(6)(A)-(E) and (k)(3) filed 5-31-91 as an emergency; operative 5-31-91 (Register 91, No. 33). A Certificate of Compliance must be transmitted to OAL by 9-30-91 or emergency language will be repealed by operation of law on the following day.
7. Amendment of section filed 9-30-91 as an emergency; operative 9-30-91 (Register 92, No. 2). A Certificate of Compliance must be transmitted to OAL 1-28-92 or emergency language will be repealed by operation of law on the following day.
8. Repealed by operation of Government Code section 11346.1(g) (Register 92, No. 12).
9. New subsections (b)(6)(A)-(F) and (k)(3) refiled 12-17-91; operative 12-17-91. Certificate of Compliance included (Register 92, No. 12).
10. Change without regulatory effect amending definitions of Chief, Department, and Director in subsection (c) filed 3-4-92 pursuant to section 100, title 1, California Code of Regulations (Register 92, No. 19).
11. New subsections (b)(5)(I)-(b)(5)(I)3. and (e)(2)(A)-(C), new subsection (g)(2)(a)3.b. and subsection relettering, new subsection (g)(9) and subsection renumbering, and amendment of subsections (b)(4)(B), (b)(5)(H), (d)(3)(A), (d)(3)(C), (d)(4)-(d)(4)(B), (d)(5)(D), (e)(1), (e)(2), (f), (f)(1), (g)(1), (g)(2)(G), (g)(8), (h)(2)(C), (i)(9), (i)(16) and newly designated subsections (g)(10) and (g)(12)(D) filed 4-26-93; operative 5-26-93 (Register 93, No. 18).
12. Editorial correction of History 9 (Register 94, No. 13).
13. Change without regulatory effect amending subsection (g)(12)(A) filed 12-14-94 pursuant to section 100, title 1, California Code of Regulations (Register 94, No. 50).
14. Repealer of note to subsection (f) filed 9-4-97; operative 10-4-97 (Register 97, No. 36).

15. Change without regulatory effect changing subsection (k) designator to subsection (j) designator filed 3-15-99 pursuant to section 100, title 1, California Code of Regulations (Register 99, No. 12).

16. Amendment of subsections (b)(5)(C), (d)(3)(C) and (d)(4)(A)-(B), new subsection (f)(10) and amendment of subsections (g)(2), (g)(2)(G), (g)(6), (g)(8) and (h)(1) filed 7-6-2004; operative 7-6-2004. Submitted to OAL for printing only pursuant to Labor Code section 142.3(a)(3) (Register 2004, No. 28).

§5194. Hazard Communication, Appendix A

Health Hazard Definitions (Mandatory)

Although safety hazards related to the physical characteristics of a substance 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 nonoccupationally 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 substances 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 obviously 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 substance 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 substances which meet any of the following definitions, as determined by the criteria set forth in Appendix B are health hazards:

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

(a) It has been evaluated by the International Agency for Research on Cancer (IARC) Monographs, Vols 1-53 and Supplements 1-8, and found to be a carcinogen or potential carcinogen; or

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

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

2. Corrosive: A substance that causes visible destruction of, or irreversible alterations in, living tissue by chemical action at the site of contact. For example, a substance 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 of four hours. This term shall not refer to action on inanimate surfaces.

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

(a) A substance 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 substance 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 substance 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 substance, which is not corrosive, but which causes a reversible inflammatory effect on living tissue by chemical action at the site of contact. A substance is a skin irritant if, when tested on the intact skin of albino rabbits by the methods of 16 CFR 1500.41 for 24 hours exposure or by other appropriate techniques, it results in an empirical score of five or more. A substance is an eye irritant if so determined under the procedure listed in 16 CFR 1500.42 or other appropriate techniques.

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

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

(a) A substance 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 substance 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 substance 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 substances 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: Substances which produce liver damage.

Signs and Symptoms: Jaundice; liver enlargement.

Substances: Carbon tetrachloride; nitrosamines.

b. Nephrotoxins: Substances which produce kidney damage.

Signs and Symptoms: Edema; proteinuria.

Substances: Halogenated hydrocarbons; uranium.

c. Neurotoxins: Substances which produce their primary toxic effects on the nervous system.

Signs and Symptoms: Narcosis; behavioral changes; decrease in motor functions.

Substances: 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.

Substances: Carbon monoxide; cyanides.

e. Agents which damage the lung: Substances which irritate or damage the pulmonary tissue.

Signs and Symptoms: Cough; tightness in chest; shortness of breath.

Substances: Silica; asbestos.

f. Reproductive toxins: Substances which affect the reproductive capabilities including chromosomal damage (mutations) and effects on fetuses (teratogenesis).

Signs and Symptoms: Birth defects; sterility.

Substances: Lead; DBCP.

g. Cutaneous hazards: Substances which affect the dermal layer of the body.

Signs and Symptoms: Defatting of the skin; rashes; irritation.

Substances: Ketones; chlorinated compounds.

h. Eye hazards: Substances which affect the eye or visual capacity.

Signs and Symptoms: Conjunctivitis; corneal damage.

Substances: Organic solvents; acids.

NOTE: Authority cited: Sections 142.3 and 6398, Labor Code. Reference: Sections 142.3 and 6361-6399.7, Labor Code; and *United Steelworkers of America v. Auchter* (3d Cir. 1985) 763 F.2d 728.

HISTORY

1. Amendment of subsections 1.(a), 1.(b) and 4. of Appendix A filed 4-26-93; operative 5-26-93 (Register 93, No. 18).

§5194. Hazard Communication, Appendix B

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. Manufacturers, importers, and employers evaluating substances 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 substances 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 not diminish the duty of the 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 subsection 5194(d)(4) and Appendix A, a determination by the National Toxicology Program, the International Agency for Research on Cancer, or OSHA that a substance 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 substances 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 substance, shall be a sufficient basis for a hazard determination and reported on any material safety data sheet. The manufacturer, importer, or employer may also report the results of other scientifically valid studies which tend to refute the findings of hazard.

NOTE: Authority cited: Sections 142.3 and 6398, Labor Code. Reference: Sections 142.3 and 6361-6399.7, Labor Code; and *United Steelworkers of America v. Auchter* (3d Cir. 1985) 763 F.2d 728.

HISTORY

1. Amendment filed 4-26-93; operative 5-26-93 (Register 93, No. 18).

§5194. Hazard Communication, Appendix C

Information Sources (Advisory)

The following is a list of available data sources which the manufacturer, importer, or employer may wish to consult to evaluate the hazards of substances 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 substance, 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 East Lincoln Avenue, Rahway, NJ 07065

IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man and Supplements, Geneva: World Health Organization, International Agency for Research on Cancer, 1972-Present (multivolume work), 49 Sheridan Avenue, Albany, NY 12210

Industrial Hygiene and Toxicology, by F. A. Patty, John Wiley & Sons, Inc., 605 Third Avenue, New York, NY 10158-0012 (multivolume work)

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 10158-0012

Chemical Hazards of the Workplace, Gloria J. Hathaway, Nick H. Proctor, James P. Hughes and Michael L. Fischman, J. P. Lipincott Company, East Washington Square, Philadelphia, PA 19105

CRC Handbook of Chemistry and Physics, CRC Press, Inc., Boca Raton, FL

Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices, American Conference of Governmental Industrial Hygienists, 6500 Glenway Avenue, Bldg. D-7, Cincinnati, OH 45211-4438

Information on the physical hazards of chemicals may be found in publications of the National Fire Protection Association, Boston, MA.

NOTE: --The following documents are on sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Out-of-print documents may be available from the National Technical Information Service (NTIS), Springfield, VA 22161. Occupational Health Guidelines (NIOSH Pub. No. 81-123). Occupational Health Guidelines, Supplement 1 (NIOSH Pub. No. 88-1188). Occupational Health Guidelines, Supplement 2 (NIOSH Pub. No. 89-104). NIOSH Pocket Guide to Chemical Hazards, NIOSH Pub. No. 90-117. 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 (latest edition). 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

OSHA's General Industry Standards (29 CFR Part 1910)

NTP Annual Report on Carcinogens and Summary of the Annual Report on Carcinogens.

BIBLIOGRAPHIC DATA BASES

Service Provider and File Name:

BRS Information Technologies, Inc., a division of Maxwell Online, Inc., 8000 Westpark Dr., McLean, VA 22102

AGRICOLA

BIOSIS PREVIEWS

CA SEARCH

DRUG INFORMATION FULL TEXT

MEDLINE

NTIS

POLLUTION ABSTRACTS

TOXLINE

DIALOG, Dialog Information Services, Inc., 3460 Hillview Avenue, Palo Alto, CA 94304

AGRICOLA

BIOSIS PREVIEWS, 1969-PRESENT

CAB ABSTRACTS 1972-PRESENT

CHEMICAL EXPOSURE 1974-PRESENT

CA SEARCH 1967-PRESENT

CHEMNAME 1967-PRESENT

CHEMSEARCH 1957-PRESENT

CONFERENCE PAPERS INDEX

EMBASE 1974-PRESENT

ENVIRONMENTAL BIBLIOGRAPHY 1973-PRESENT

ENVIROLINE 1971-PRESENT

FEDERAL RESEARCH IN PROGRESS

FOOD SCIENCE & TECHNOLOGY ABSTRACTS

FOODS ADLIBRA

INTL. PHARMACEUTICAL ABSTRACTS

LIFE SCIENCES COLLECTION 1978-PRESENT

NTIS

OCCUPATIONAL SAFETY AND HEALTH (NIOSH) 1973-PRESENT

PAPERCHEM 1967-PRESENT

POLLUTION ABSTRACTS

SCISEARCH 1974-PRESENT

Orbit Search Service, a division of Maxwell Online, Inc., 8000 Westpark Dr., McLean, VA 22102

CHEMICAL ABSTRACTS

CHEMDEX

ENVIROLINE

LABORDOC

NTIS

Fein-Marquart Associates (FMA), Chemical Information Systems, Inc. (CIS), 7215 Yorke Road, Baltimore, MD 21212

Structure & Nomenclature Search System (SANSS)

RTECS

Clinical Toxicology of Commercial Products (CTCP)

Oil and Hazardous Materials Technical Assistance Data System

MEDLARS Management Section, National Library of Medicine, Department of Health and Human Services, Public Health Service, National Institutes of Health, 8600 Rockville Pike, Bethesda, MD 20894

BACKFILES

CANCERLIT

CHEMLINE

HAZARDOUS SUBSTANCES DATABANK

MEDLINE

RTECS

SDILINE

TOXLINE

TOXLINE65

TOXLIT

TOXLIT65

TOXNET/TOXICOLOGIC DATA & TRI

Questel, Inc., 2300 Clarendon Blvd., Suite 1111, Arlington, VA 22201

CIS/ILO

NOTE: Sections 142.3 and 6398, Labor Code. Reference: Sections 142.3 and 6361-6399.7, Labor Code; and United Steelworkers of America v. Auchter (3d Cir. 1985) 763 F.2d 728.

HISTORY

1. Amendment filed 4-26-93; operative 5-26-93 (Register 93, No. 18).

§5194. Hazard Communication, Appendix D

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 Section 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 the 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 know 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 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. 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 rewording or otherwise encouraging the development of secret processes or devices. The protection is merely against a 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 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.

NOTE: Authority cited: Sections 142.3 and 6398, Labor Code. Reference: Sections 142.3 and 6361-6399.7, Labor Code; and *United Steelworkers of America v. Auchter* (3d Cir. 1985) 763 F.2d 728.

§5194. Hazard Communication, Appendix E

Terms and Provisions for subsection (b)(6)

The following Sections from Title 22 of the California Code of Regulations (22 CCR) in effect on May 9, 1991 are printed in this Appendix because they provide terms and provisions referred to in subsection (b)(6):

12201. Definitions.

(a) In The Course of doing Business.

For purposes of Health and Safety Code Sections 25249.5 and 25249.6, "in the course of doing business" means any act or omission , whether or not for profit, except:

(1) as excluded by subdivision (b) of Section 25249.11 of the Health and Safety Code; or

(2) when caused by acts of war or grave and irresistible natural disasters such that no reasonable amount of resistance or advance preparation would be sufficient to avoid the discharge, release or exposure.

(b) In the Course of Doing Business, Acts of Employees.

"In the course of doing business" includes any act or omission of any employee which furthers the purpose or operation of the business, or which is expressly or implicitly authorized, except for the personal use, consumption or production of listed chemicals by an employee on the business premises or while performing activities for the business, unless the employer knows or should know of such use, consumption or production and knows or should know that such use, consumption or production will expose other individuals within the meaning of Health and Safety Code Section 25249.6 to a listed chemical.

(c) Employee.

The term "employee" shall have the same meaning as it does in Unemployment Insurance Code Section 621 and in Labor Code Section 3351. Generally, and without limiting the applicability of the definitions in these two statutes, this means that an employee is a person who performs services for remuneration under any appointment or contract of hire or apprenticeship, express or implied, oral or written, whether lawfully or unlawfully employed. In computing whether a person employs ten or fewer employees in his business, all full-time and part-time employees on the date on which the discharge, release or exposure occurs must be counted. Thus, the prohibitions on discharge or release and exposures to certain chemicals will apply to any person who has ten or more full-time or part-time employees on the date in question.

(d) Knowingly.

"Knowingly" refers only to knowledge of the fact that a discharge of, release of, or exposure to a chemical listed pursuant to Health and Safety Code Section 25249.8(a) is occurring. No knowledge that the discharge, release or exposure is unlawful is required. However, a person in the course of doing business who, through misfortune or accident and without evil design, intention or negligence, commits an act or omits to do something which results in a discharge, release or exposure has not violated Health and Safety Code Sections 25249.5 or 25249.6.

(e) ED NOTE: Cal-OSHA Standards Board did not incorporate subsection (e) into 5194(b)(6).

(f) Expose.

The term "expose" means to cause to ingest, inhale, contact via body surfaces or otherwise come into contact with a chemical. An individual may come into contact with a chemical through water, air, food, consumer products and any other environmental exposure as well as occupational or workplace exposures.

(g) - (j) ED NOTE: Cal-OSHA Standards Board did not incorporate subsections (g), (h), (i), and (j) into 5194(b)(6).

(k) For purposes of this chapter, "listed chemical" means a chemical listed pursuant to Health and Safety Code Section 25249.8, subsection (a).

12502. Exposure to a Listed Chemical in Drinking Water.

(a) A person otherwise responsible for an exposure to a listed chemical which involves the use of drinking water, including the use of drinking water in food or any other consumer product, does not "expose" an individual within the meaning of Section 25249.6 to the extent that the person can show that the listed chemical was contained in drinking water which was received from:

(1) a public water system, as defined in Section 4010.1 of the Health and Safety Code;

(2) a commercial supplier of drinking water; or

(3) a source of drinking water in compliance with all applicable primary drinking water standards for all listed chemicals and the chemical in question is the result of treatment of the water in order to achieve compliance with primary drinking water standards.

Where the source of the listed chemical is in part from such drinking water and in part from other sources, "exposure" can occur only as to that portion of the listed chemical from sources other than such drinking water.

(b) For purposes of subdivision (a), the amount of a listed chemical contained in drinking water shall be determined by sampling of the drinking water at the point of delivery and by testing pursuant to Section 12901. If sampling and testing is impractical, the amount of a listed chemical shall be based on test results of the most recent sample of the drinking water taken by the public water system or the commercial drinking water supplier, provided that all sampling and testing has been conducted at the frequency and in the manner required by law, or alternatively, such amount shall be calculated at five percent of the maximum contaminant level set forth in the primary drinking water standard for the listed chemical.

12601. Clear and Reasonable Warnings.

(a) Whenever a clear and reasonable warning is required under Section 25249.6 of the Health and Safety Code, the method employed to transmit the warning must be reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure. The message must clearly communicate that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm. Nothing in this section shall be construed to preclude a person from providing warnings other than those specified in subdivisions (b), (c), and (d) which satisfy the requirements of this subdivision, or to require that warnings be provided separately to each exposed individual.

(b) Warnings for consumer products exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed to be clear and reasonable. A "consumer products exposure" is an exposure which results from a person's acquisition, purchase, storage, consumption, or other reasonably foreseeable use of a consumer good, or any exposure that results from receiving a consumer service.

(1) The warning may be provided by using one or more of the following methods singly or in combination:

(A) A warning that appears on a product's label or other labeling. The term "label" means a display of written, printed or graphic matter upon a product or its immediate container. The term "labeling" means any label or other written, printed or graphic matter affixed to or accompanying a product or its container or wrapper.

(B) Identification of the product at the retail outlet in a manner which provides a warning. Identification may be through shelf labeling, signs, menus, or a combination thereof.

(C) A system of signs, public advertising identifying the system and toll-free information services, or any other system, that provides clear and reasonable warnings.

(D) For alcoholic beverages, including, without limitation, beer, malt beverages, wine and distilled spirits:

1. Primarily intended for consumption off the premises where sold or distributed:

(i) at least one notice or sign, no smaller than 10 inches wide by 10 inches high, and bearing the warning message set forth in paragraph (4) (E) of this subsection; or

(ii) at least one horizontal strip marker no smaller than 10 1/2 inches wide by 1 1/4 inches high, and bearing the warning message set forth in paragraph (4)(E) of this subsection; or

(iii) a notice no smaller than 5 inches by 5 inches, and bearing the warning message set forth in (4)(E) of this subsection.

(iv) If signs 10 inches high by 10 inches wide are used, the word "warning" shall be centered, three-quarters of an inch from the top of the sign in ITC Garamond bold condensed type face all in one-inch capital letters. Three-sixteenths of an inch from the base of the word "warning" shall be a line extending from left to right across the width of the sign one-sixteenth of an inch in thickness. Centered one-half inch below the line shall be the body of the warning message in 36/50 ITC Garamond bold condensed type face with the initial letter of each word, other than the conjunctive "and," capitalized. For the body of the warning message, left and right margins of at least one-half of an inch, and a bottom margin of at least one-half inch shall be observed. Larger signs shall bear substantially the same proportions of type size and spacing to sign dimension as the sign 10 inches high by 10 inches wide.

(v) If the 10 1/2 inch by 1 1/4 inch horizontal strip markers are used, the word "WARNING," punctuated by a colon, shall be justified left and located three-sixteenths of an inch from the top of the strip notice in ITC Garamond bold condensed type face all in capital letters measuring eleven sixteenth of an inch in height.

Three thirty-seconds of an inch from the base of the word "WARNING" shall be a line extending from left to right across the width of the word "WARNING" and the punctuation colon one thirty-second of an inch in thickness. Located one-fourth of an inch from the top and one-fourth of an inch from the bottom of the strip notice, and to the immediate right of the word "WARNING," shall be the body of the warning message in 12/16 point ITC Garamond bold condensed type face with the initial letter of each word, other than the conjunctive "and," capitalized. The word "WARNING" shall be one-half inch from the left edge of the strip notice and the requisite warning message shall extend to within one-half inch from the right edge.

(vi) If the 5 inch by 5 inch signs are used, they shall bear substantially the same proportions of type size and spacing to sign dimension as the sign 10 inches high by 10 inches wide, with both the word "WARNING" and the warning text set in white on a contrasting red background.

(vii) Such sign or notice shall be placed in the retail establishment so as to assure that it is readable and likely to be read either at each retail point of sale or each point of display. Such sign or notice shall be placed either at all retail points of sale or all points of display, but need not be placed at both. If 10 inch by 10 inch signs or notices are placed at the point of display, each shall be placed no more than ten feet from any alcoholic beverage container and in a manner associating the sign or notice with the display. If horizontal strip notices are used, they shall be placed at ten foot intervals horizontally along the display. If a 5 inch by 5 inch sign is used, it shall be conspicuously placed at each retail point of sale (e.g., check-out counter, cash register, cash box) so that it is likely to be read and understood during the sales transaction.

(viii) All measurements specified or referred to in paragraphs (iv), (v) and (vi), above, are not required to be precisely accurate.

2. Provided for consumption on the premises at tables served by food or beverage persons, or sold or distributed through over the counter service;

(i) a notice or sign displayed at each of the tables where alcoholic beverages are served or may be consumed at least 5 inches high by 5 inches wide bearing substantially the same type face and substantially the same proportion of type size and spacing to sign dimension as described in paragraph (D)1. (vi); or

(ii) the warning message set forth in paragraph (4)(E) of this subdivision, placed upon a menu or list in association with the alcoholic beverages listed thereon and served at such premises, or if alcoholic beverages are not listed thereon, on any menu or list provided to patrons in association with the listing of food or beverage

offerings, in type size and design, such that the text is conspicuous and likely to be read prior to consumption of alcoholic beverages or,

(iii) at least one 10 inch by 10 inch sign, meeting the specifications set forth in paragraph (D)1. (iv) of this subsection, placed so that it is readable and likely to be read by patrons as they enter each public entrance to the establishment. If the establishment does not have clearly defined physical boundaries delineating those areas where, by permit or license, alcoholic beverages are served, the 10 inch by 10 inch sign shall be posted so that it is readable and likely to be read by patrons as they enter the area or areas where, by permit or license, alcoholic beverages are served; and

(iv) If sold or distributed through over-the-counter service, at least one sign, meeting the specifications set forth in paragraph (D)1., (iv) of this subsection, placed in the retail establishment so that the warning message is, prior to the consumption of alcoholic beverages, readable and likely to be read from all counter locations available to the public. Therefore, a retail establishment providing a warning pursuant to the preceding sentence, also would be required to provide a warning in accordance with either paragraph 2.(i), 2.(ii) or 2.(iii) of this subsection.

3. For premises which are specially licensed to sell and serve alcoholic beverages both on and off the licensed premises (e.g., in facilities that offer both "tasting" and retail sales), the off-sale portion of the premises shall comply with the provisions of subsection (D)1., above, and the portion of the premises where alcoholic beverages are served shall comply with the provisions of subsection (D)2., above.

4. For alcoholic beverages sold or distributed to consumers through the mail or package delivery services, warnings may be provided by incorporating or placing the warning message set forth in paragraph (4)(E) on or in the shipping container or delivery package in such a manner so that the warning message is likely to be read by the recipient prior to consumption of the alcoholic beverage(s).

5. All signs or notices referred to in subsections (D)1., (D)2. and (D)3., above, shall be displayed so that they are clearly visible under all lighting conditions normally encountered during business hours.

(2) To the extent practicable, warning materials such as signs, notices, menu stickers, or labels shall be provided by the manufacturer, producer, or packager of the consumer product, rather than by the retail seller. For alcoholic beverages, the placement and maintenance of the warning shall be the responsibility of the manufacturer or its distributor at no cost to the retailer, and any consequences for failure to do the same shall rest solely with the manufacturer or its distributor, provided that the retailer does not remove, deface, or obscure the requisite signs or notices, or obstruct, interfere with, or otherwise frustrate the manufacturer's reasonable efforts to post, maintain, or periodically replace said materials. For prescription drugs, the labeling approved or otherwise provided under federal law and the prescriber's accepted practice of obtaining a patient's informed consent shall be deemed to be a clear and reasonable warning.

(3) The warnings provided pursuant to paragraphs (1)(A) and (1)(B) shall be prominently placed upon a product's label or other labeling or displayed at the retail outlet with such conspicuousness, as compared with other words, statements, designs, or devices in the label, labeling or display as to render it likely to be read and understood by an ordinary individual under customary conditions of purchase or use.

(4) The warning message must include the following language:

(A) For consumer products that contain a chemical known to the state to cause cancer:

"WARNING: This product contains a chemical known to the State of California to cause cancer."

(B) For consumer products that contain a chemical known to the state to cause reproductive toxicity:

"WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."

(C) For food, other than alcoholic beverages, sold, served, or otherwise provided in food facilities, as defined in Health and Safety Code Section 27521(a), which is intended for immediate consumption:

"WARNING: Chemicals known to the State of California to cause cancer, or birth defects or other reproductive harm may be present in foods or beverages sold or served here."

(D) For fresh fruits, nuts and vegetables:

"WARNING: This product may contain a chemical known to the State of California to cause cancer, or birth defects or other reproductive harm."

(E) For alcoholic beverages, including, without limitation, beer, malt beverages, wine and distilled spirits:

"WARNING: Drinking Distilled Spirits, Beer, Coolers, Wine and Other Alcoholic Beverages May Increase Cancer Risk, and, During Pregnancy, Can Cause Birth Defects."

(5) A person in the course of doing business, who manufactures, produces, assembles, processes, handles, distributes, stores, sells or otherwise transfers a consumer product which he or she knows to contain a chemical known to the state to cause cancer or reproductive toxicity in an amount which requires a warning shall provide a warning to any person to whom the product is sold or transferred unless the product is packaged or labeled with a clear and reasonable warning.

(c) Warnings for occupational exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed clear and reasonable. An "occupational exposure" is an exposure, in the workplace of the employer causing the exposure, to any employee.

(1) The method employed to transmit the warning must include one of the following alternative methods:

(A) A warning that appears on the label or labeling of a product or substance present or used in the workplace. The label or labeling shall be prominently displayed on the product or substance and the product or substance shall be used under circumstances which make it likely that the warnings will be read and understood by employees or other individuals prior to the exposure for which the warning is given.

(B) A warning that appears on a sign in the workplace posted in a conspicuous place and under conditions that make it likely to be read and understood by employees and other individuals prior to the exposure for which the warning is given.

(C) A warning to the exposed employee about the chemical in question which complies with all information, training and labeling requirements of the federal Hazard Communication Standard (29 CFR Section 1910.1200, as amended and filed September 30, 1986), the California Hazard Communication Standard (Cal. Code Regs., Title 8, Section 5194, as amended and filed May 26, 1987) , or , for pesticides, the Pesticides and Worker Safety requirements (Cal. Code Regs., Title 3, Ch. 6, Subch. 3, Group 3, Section 6700 et seq., in effect on February 16, 1988) authorized in Food and Agricultural Code Section 12981 (as amended by Statutes of 1980, Ch. 926, P. 2945, Section 1).

(2) For purposes of paragraph (1)(A) of this subdivision, the warning shall be provided in terms which would provide a clear warning for a consumer product as specified above.

(3) For purposes of paragraph (1)(B) of this subdivision, the following specific warning messages shall be deemed to clearly communicate that an individual is being exposed to a chemical known to the state to cause cancer, or birth defects or other reproductive harm.

(A) For exposure to a chemical known to the state to cause cancer:

"WARNING: This area contains a chemical known to the State of California to cause cancer."

(B) For exposure to a chemical known to the state to cause reproductive toxicity:

"WARNING: This area contains a chemical known to the State of California to cause birth defects or other reproductive harm."

(d) Warnings for environmental exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed clear and reasonable. An "environmental exposure" is an exposure which may foreseeably occur as the result of contact with an environmental medium, including, but not limited to, ambient air, indoor air, drinking water, standing water, running water, soil, vegetation, or manmade or natural substances, either through inhalation, ingestion, skin contact or otherwise. Environmental exposures include all exposures which are not consumer products exposures, or occupational exposures.

(1) The method employed to transmit the warning must include the most appropriate of the following alternative methods under the circumstances:

(A) A warning that appears on a sign in the affected area. The term "sign" means a presentation of written, printed or graphic matter. The term "affected area" means the area in which an exposure to a chemical known to the state to cause cancer or reproductive toxicity is at a level that requires a warning. A posting of signs in the manner described in Section 6776, (e)(1) of Title 3 of the California Code of Regulations, (as amended and filed August 15, 1986) shall be sufficient for purposes of this paragraph.

(B) A warning which is in a notice mailed or otherwise delivered to each occupant in the affected area. Such notice shall be provided at least once in any three-month period.

(C) A warning provided by public media announcements which target the affected area. Such announcements shall be made at least once in any three-month period.

(2) Environmental exposure warnings shall be provided in a conspicuous manner and under such conditions as to make it likely to be read, seen or heard and understood by an ordinary individual in the course of normal daily activity, and reasonably associated with the location and source of the exposure.

(3) For purposes of paragraph (1)(A) of this subdivision, the following specific warning messages shall be deemed to clearly communicate that an individual is being exposed to a chemical known to the state to cause cancer, or birth defects or other reproductive harm.

(A) For exposure to a chemical known to the state to cause cancer:

"WARNING: This area contains a chemical known to the State of California to cause cancer."

(B) For exposure to a chemical known to the state to cause reproductive toxicity:

"WARNING: This area contains a chemical known to the State of California to cause birth defects or other reproductive harm."

12701. General.

(a) The determination of whether a level of exposure to a chemical known to the state to cause cancer poses no significant risk for purpose of Health and Safety Code Section 25249.10(c) shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical as known to the state to cause cancer. Nothing in this article shall preclude a person from using evidence, standards, risk assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure to a listed chemical poses no significant risk.

(b) A level of exposure to a listed chemical, assuming daily exposure at that level, shall be deemed to pose no significant risk provided that the level is determined:

(1) By means of a quantitative risk assessment that meets the standards described in Section 12703;

(2) By application of Section 12707 (Routes of Exposure); or

(3) By one of the following, as applicable:

(A) If a specific regulatory level has been established for the chemical in question in Section 12705, by application of that level.

(B) If no specific level is established for the chemical in question in Section 12705, by application of Section 12709 (Exposure to Trace Elements), 12711 (Levels Based on State or Federal Standards) or 12713 (Exposure to Food, Drugs, Cosmetics and Medical Devices), unless otherwise provided.

(c) ED NOTE: Cal-OSHA Standards Board did not incorporate subsection (c) into 5194(b)(6).

(d) This article establishes exposure levels posing no significant risk solely for purposes of Health and Safety Code Section 25249.10(c). Nothing in this article shall be construed to establish exposure or risk levels for other regulatory purposes.

12703. Quantitative Risk Assessment.

(a) A quantitative risk assessment which conforms to this section shall be deemed to determine the level of exposure to a listed chemical which, assuming daily exposure at that level, poses no significant risk. The assessment shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for listing the chemical as known to the state to cause cancer. In the absence of principles or assumptions scientifically more appropriate, based upon the available data, the following default principles and assumptions shall apply in any such assessment:

(1) Animal bioassay studies for quantitative risk assessment shall meet generally accepted scientific principles, including the thoroughness of experimental protocol, the degree to which dosing resembles the expected manner of human exposure, the temporal exposure pattern, the duration of study, the purity of test material, the number and size of exposed groups, the route of exposure, and the extent of tumor occurrence.

(2) The quality and suitability of available epidemiologic data shall be appraised to determine whether the study is appropriate as the basis of a quantitative risk assessment, considering such factors as the selection of the

exposed and reference groups, reliable ascertainment of exposure, and completeness of follow-up. Biases and confounding factors shall be identified and quantified.

(3) Risk analysis shall be based on the most sensitive study deemed to be of sufficient quality.

(4) The results obtained for the most sensitive study deemed to be of sufficient quality shall be applicable to all routes of exposure for which the results are relevant.

(5) The absence of a carcinogenic threshold dose shall be assumed and no-threshold models shall be utilized. A linearized multistage model for extrapolation from high to low doses, with the upper 95 percent confidence limit of the linear term expressing the upper bound of potency shall be utilized. Time-to-tumor models may be appropriate where data are available on the time of appearance of individual tumors, and particularly when survival is poor due to competing toxicity.

(6) Human cancer potency shall be derived from data on human or animal cancer potency. Potency shall be expressed in reciprocal milligrams of chemical per kilogram of bodyweight per day. Interspecies conversion of animal cancer potency to human cancer potency shall be determined by multiplying by a surface area scaling factor equivalent to the ratio of human to animal bodyweight, taken to the one-third power. This is equivalent to a scaling factor of 14 when extrapolating from mouse data, and a scaling factor of 6.5 when extrapolating from rat data.

(7) When available data are of such quality that physiologic, pharmacokinetic and metabolic considerations can be taken into account with confidence, they may be used in the risk assessment for inter-species, inter-dose, and inter-route extrapolations.

(8) When the cancer risk applies to the general population, human body weight of 70 kilograms shall be assumed. When the cancer risk applies to a certain subpopulation, the following assumptions shall be made, as appropriate:

<i>Subpopulation</i>	<i>Kilograms of Body Weight</i>
Man (18+ years of age)	70
Woman (18+ years of age)	58
Woman with conceptus	58
Adolescent (11-18 years of age)	40
Child (2-10 years of age)	20
Infant (0-2 years of age)	10

(b) For chemicals assessed in accordance with this section, the risk level which represents no significant risk shall be one which is calculated to result in one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question, except where sound considerations of public health support an alternative level, as, for example:

(1) where chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination; or

(2) where chlorine disinfection in compliance with all applicable state and federal safety standards is necessary to comply with sanitation requirements; or

(3) where a clean-up and resulting discharge is ordered and supervised by an appropriate governmental agency or court of competent jurisdiction.

12705. Specific Regulatory Levels Posing No Significant Risk.

(a) Daily exposure to a chemical at a level which does not exceed the level set forth in subsection (b) for such chemical shall be deemed to pose no significant risk within the meaning of Health and Safety Code section 25249.10(c).

(b)

<i>Chemical Name</i>	<i>Level micrograms/day</i>
Acrylonitrile	0.7
Aldrin	0.04
Asbestos	100 fibers inhaled/day*
Benzene	7
Benzidine	0.001
Bis(2-chloroethyl) ether	0.3
Bis(chloromethyl) ether	0.02
Carbon tetrachloride	5
DDT, DDE and DDD (in combination)	2
1,2-Dibromo-3-chloropropane (DBCP)	0.1
para-Dichlorobenzene	20
3,3'-Dichlorobenzidine	0.6
Dieldrin	0.04
1,4-Dioxane	30
Epichlorohydrin	9
Ethylene dibromide 3 (inhalation)	0.2 (ingestion)
Ethylene dichloride	10
Ethylene oxide	2
Hexachlorobenzene	0.4
Hexachlorocyclohexane (technical grade)	0.2
N-Nitroso-n-dibutylamine	0.06
N-Nitrosodiethylamine	0.02
N-Nitrosodimethylamine	0.04
N-Nitrosodiphenylamine	80
N-Nitrosodi-n-propylamine	0.1
N-Nitroso-N-ethylurea	0.03
N-Nitroso-N-methylurea	0.006
Polybrominated biphenyls	0.02
Toxaphene	0.6
2,4,6-Trichlorophenol	10
Urethane	0.7

*Fibers equal to or greater than 5 micrometers in length and 0.3 micrometers in width, with a length to width ratio of greater than or equal to 3:1 as measured by phase contrast microscopy.

(c) Whenever the lead agency proposes to formally adopt, pursuant to this section, a level which shall be deemed to pose no significant risk of cancer, assuming daily exposure at that level, the lead agency shall provide to each member of the Scientific Advisory Panel notice of the proposed action, a copy of the proposed level, and a copy of initial statement of reasons supporting the proposal. The close of the public comment period for any such proposal shall be scheduled by the lead agency so as to permit the Scientific Advisory Panel the opportunity to review such proposal and provide comment to the lead agency. Any such comment by the Scientific Advisory Panel shall become a part of the formal rulemaking file. Nothing in this subdivision shall be

construed to prevent members of the Scientific Advisory Panel from providing comments individually on any such proposal, or to require the Scientific Advisory Panel to submit any comment.

12707. Routes of Exposure.

(a) Where scientifically valid absorption studies conducted according to generally accepted standards demonstrate that absorption of a chemical through a specific route of exposure can be reasonably anticipated to present no significant risk of cancer at levels of exposure not in excess of current regulatory levels, the lead agency may identify the chemical as presenting no significant risk by that route of exposure. Any exposure, discharge or release of a chemical so identified shall be deemed to present no significant risk to the extent that it results in exposure to humans by the identified route, and does not exceed the level established in any other applicable federal or state standard, regulation, guideline, action level, license, permit, condition, requirement or order.

(b) The following chemicals present no significant risk of cancer by the route of ingestion:

- (1) Asbestos
- (2) Beryllium and beryllium compounds
- (3) Cadmium and cadmium compounds
- (4) Chromium (hexavalent compounds)
- (5) Nickel and nickel compounds

12709. Exposure to Trace Elements.

(a) Except where a specific regulatory level is established in Section 12705, exposure to a trace element listed in (b) shall be deemed to pose no significant cancer risk so long as the reasonably anticipated level of exposure to the chemical does not exceed the level set forth in (b).

(b)

<i>Element</i>	<i>No Significant Risk Level in micrograms per day</i>
Arsenic (inorganic)	10
Beryllium	0.1
Cadmium	1

12711. Levels Based on State or Federal Standards.

(a) Except as otherwise provided in section 12705, 12707, 12709, or 12713, levels of exposure deemed to pose no significant risk may be determined as follows:

(1) Where a state or federal agency has developed a regulatory level for a chemical known to the state to cause cancer which is calculated to result in not more than one excess case of cancer in an exposed population of 100,000, such level shall constitute the no significant risk level.

(2) The following levels based on state or federal risk assessments shall be deemed to pose no significant risk:

<i>Chemical Name</i>	<i>Level micrograms/day</i>
Acetaldehyde	90
Acrylamide	0.2
Allyl chloride	30
Aniline	100
Azobenzene	6
Benzo (a) pyrene	0.06
Beryllium oxide	0.1
Beryllium sulfate	0.0002
1,3-Butadiene	0.4
Chlordane	0.5
Chloroform	9
Chromium (hexavalent)	0.001
Coke oven emissions	0.3
DDVP (Dichlorvos)	2
Dichloromethane (Methylene Chloride)	50
Di (2-ethylhexyl) phthalate	80
2,4-Dinitrotoluene	2
Folpet	200
Formaldehyde (gas)	15
Furmecyclox	20
Heptachlor	0.2
Heptachlor epoxide	0.08
Hexachlorocyclohexane	
alpha isomer	0.3
beta isomer	0.5
gamma isomer	0.6
Hydrazine	0.04
Hydrazine sulfate	0.2
4,4'-Methylene bis (N,N-dimethyl)benzeneamine	20
Nickel refinery dust	0.8
Nickel subsulfide	0.4
N-Nitrosodiethanolamine	0.3
N-nitrosomethylethylamine	0.03
N-nitrosopyrrolidine	0.3
Pentachlorophenol	40
Polychlorinated Biphenyls (PCBs)	0.09
Tetrachlorodibenzo-p-dioxin (TCDD)	0.000005
Tetrachloroethylene	14
Trichlorethylene	60
Vinyl chloride	0.3

(3) For drinking water, the following levels shall be deemed to pose no significant risk:

(A) Drinking water maximum contaminant levels adopted by the Department of Health Services for chemicals known to the state to cause cancer;

(B) Drinking water action levels for chemicals known to the state to cause cancer for which maximum contaminant levels have not been adopted;

(C) Specific numeric levels of concentration for chemicals known to the state to cause cancer which are permitted to be discharged or released into sources of drinking water by a Regional Water Quality Control Board in a water quality control plan or in waste discharge requirements, when such levels are based on considerations of minimizing carcinogenic risks associated with such discharge or release.

12721. Level of Exposure to Carcinogens.

(a) For the purposes of the Act, "level in question" means the chemical concentration of a listed chemical for the exposure in question. The exposure in question includes the exposure for which the person in the course of doing business is responsible, and does not include exposure to a listed chemical from any other source or product.

(b) For purposes of the Act, "lifetime exposure" means the reasonably anticipated rate of exposure for an individual to a given medium of exposure measured over a lifetime of seventy years.

(c) For purposes of Health and Safety Code Section 25249.10(c), the level of exposure to a listed carcinogen, assuming lifetime exposure at the level in question, shall be determined by multiplying the level in question (stated in terms of a concentration of a chemical in a given medium) times the reasonably anticipated rate of exposure for an individual to the given medium of exposure measured over a lifetime of seventy years.

(d) The following assumptions shall be used to calculate the reasonably anticipated rate of exposure to a listed carcinogen, unless more specific and scientifically appropriate data are available:

(1) For an exposure reasonably expected to affect the general population in any geographic area:

(A) The exposed individual ingests two liters of drinking water per day.

(B) The exposed individual inhales twenty cubic meters of air per day.

(C) The exposed individual has a lifespan of seventy years.

(2) For an exposure reasonably anticipated to affect a certain subpopulation of the general population in any geographic area, specific data (if available) relating to that subpopulation shall be used to determine the level of exposure.

(A) In the absence of more specific and scientifically appropriate data, the following assumptions should be made as appropriate:

<i>Subpopulation</i>	<i>Water liters/day</i>	<i>Air cubic meters/day</i>
Man (18+ years of age)	2	20
Woman (18+ years of age)	2	20
Woman with conceptus	2	20
Adolescent (10-18 years of age)	2	20
Child (2-10 years of age)	2	15
Infant (0-2 years of age)	1	4

(B) For an exposure reasonably expected to affect the conceptus (embryo or fetus), the gestation period for the exposed conceptus is nine months.

(3) For workplace exposures, the exposed worker inhales ten cubic meters of workplace air per eight-hour day, forty hours per week, fifty weeks per year over a forty-year period. The exposed individual from the general population who occasionally enters a workplace inhales 1.25 cubic meters of workplace air for one hour per month for a seventy-year lifetime.

(4) For exposures to consumer products, lifetime exposure shall be calculated using the average rate of intake or exposure for average users of the consumer product, and not on a per capita basis for the general population. The average rate of intake or exposure shall be based on data for use of a general category or categories of

consumer products, such as the United States Department of Agriculture Home Economic Research Report, Foods Commonly Eaten by Individuals: Amount Per Day and Per Eating Occasion, where such data are available.

12801. General.

(a) The determination of whether a level of exposure to a chemical known to the state to cause reproductive toxicity has no observable effect for purposes of Health and Safety Code Section 25249.10(c) shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of a chemical as known to the state to cause reproductive toxicity. Nothing in this article shall preclude a person from using evidence, standards, assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure has no observable effect at one thousand (1,000) times the level in question.

(b) A level of exposure to a listed chemical shall be deemed to have no observable effect, assuming exposure at one thousand times that level, provided that the level is determined:

(1) By means of an assessment that meets the standards described in section 12803 to determine the maximum dose level having no observable effect, and dividing that level by one thousand (1,000) to arrive at the maximum allowable dose level; or

(2) By application of a specific regulatory level for the chemical in question as provided in section 12805.

(c) For purposes of this article, "NOEL" shall mean that no observable effect level, which is the maximum dose level at which a chemical has no observable reproductive effect.

(d) The chemicals specifically contained in this article do not include all listed reproductive toxicants for which there is a level of exposure which has no observable effect assuming exposure at one thousand times the level in question. The fact that a chemical does not specifically appear in this article does not mean that it has an observable effect at any level.

(e) This article establishes exposure levels solely for purposes of Health and Safety Code Section 25249.10(c). Nothing in this article shall be construed to establish exposure levels for other regulatory purposes.

12803. Assessment.

(a) A quantitative risk assessment which conforms to this section shall be deemed to determine the level of exposure to a listed chemical which has no observable effect, assuming exposure at one thousand times the level in question. The assessment shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for listing the chemical as known to the state to cause reproductive toxicity. In the absence of principles or assumptions scientifically more appropriate, based upon the available data, the following default principles and assumptions shall apply in any such assessment:

(1) Only studies producing the reproductive effect which provides the basis for the determination that a chemical is known to the state to cause reproductive toxicity shall be utilized for the determination of the NOEL. Where multiple reproductive effects provide the basis for the determination that a chemical is known to the state to cause reproductive toxicity, the reproductive effect for which studies produce the lowest NOEL shall be utilized for the determination of the NOEL. The NOEL shall be the highest dose level which results in no observable reproductive effect, expressed in milligrams of chemical per kilogram of bodyweight per day.

(2) The quality and suitability of available epidemiologic data shall be appraised to determine whether the study is appropriate as the basis of an assessment considering such factors as the selection of the exposed and reference groups, the reliable ascertainment of exposure, and completeness of follow-up. Biases and confounding factors shall be identified and quantified.

(3) Animal bioassay studies for assessment shall meet generally accepted scientific principles, including the thoroughness of experimental protocol, the degree to which dosing resembles the expected manner of human exposure, the temporal exposure pattern, the duration of study, the purity of test material, the number and size of exposed groups, and the route of exposure and the extent of occurrence of effects.

(4) The NOEL shall be based on the most sensitive study deemed to be of sufficient quality.

(5) The results obtained for the most sensitive study deemed to be of sufficient quality shall be applicable to all routes of exposure for which the results are relevant.

(6) When available data are of such quality that anatomic, physiologic, pharmacokinetics and metabolic considerations can be taken into account with confidence, they may be used in the assessment.

(7) When data do not allow the determination of a NOEL, the lowest observable effect level (LOEL) shall be divided by 10 to establish a NOEL for purposes of assessment.

(b) The NOEL shall be converted to a milligram per day dose level by multiplying the assumed human body weight by the NOEL. When the applicable reproductive effect is upon the male, human body weight of 70 kilograms shall be assumed. When the applicable reproductive effect is upon the female or conceptus, human body weight of 58 kilograms shall be assumed.

12805. Specific Regulatory Levels: Reproductive

Toxicants.

(a) Exposure to a chemical at a level which does not exceed the level set forth in subsection (b) for such chemical has no observable effect assuming exposure at one thousand (1,000) times that level.

(b)	<i>Level</i>
<i>Chemical Name</i>	<i>Micrograms/day</i>
Ethylene Oxide.....	20.0
Lead.....	0.5

(c) Unless a specific level is otherwise provided in this section, an assessment by an agency of the state or federal government that is the substantial equivalent of the assessment described in subdivision (a) of Section 12803, and establishes a maximum allowable daily dose level in the manner provided in paragraph (b)(1) of Section 12801, shall constitute the allowable daily dose level having no observable effect within the meaning of Health and Safety Code Section 25249.10(c).

12821. Level of Exposure to Reproductive Toxicants.

(a) For purposes of the Act, "level in question" means the chemical concentration of a listed chemical for the exposure in question. The exposure in question includes the exposure for which the person in the course of doing business is responsible, and does not include exposure to a listed chemical from any other source or product.

(b) For purposes of Health and Safety Code Section 25249.10(c), the level of exposure to a listed reproductive toxicant shall be determined by multiplying the level in question (stated in terms of a concentration of a chemical in a given medium) times the reasonably anticipated rate of exposure for an individual to a given medium. The reasonably anticipated rate of exposure shall be based on the pattern and duration of exposure that is relevant to the reproductive effect which provided the basis for the determination that a chemical is known to the state to cause reproductive toxicity. (For example, an exposure of short duration is appropriate for a teratogenic chemical, whereas a chronic or protracted exposure is appropriate for one that retards fetal growth).

(c) The following assumptions shall be used to calculate the reasonably anticipated rate of exposure to a listed reproductive toxicant, unless more specific and scientifically appropriate data are available:

(1) The assumptions set forth in subdivision (d) of Section 12721 shall be used to calculate the reasonably anticipated rate of exposure to a listed reproductive toxicant, unless more specific and scientifically appropriate data are available.

(2) For exposures to consumer products, the level of exposure shall be calculated using the reasonably anticipated rate of intake or exposure for average users of the consumer product, and not on a per capita basis for the general population. The rate of intake or exposure shall be based on data for use of a general category or categories of consumer products, such as the United States Department of Agriculture Home Economic Research Report, Foods Commonly Eaten by Individuals: Amount Per Day and Per Eating Occasion, where such data are available.

(3) Where a maternal exposure to a listed reproductive toxicant has an effect on the conceptus (embryo or fetus), the level of exposure shall be based on the reasonably anticipated rate of exposure for the mother during the nine-month gestation period.

12901. Methods of Detection.

(a) For purposes of Section 25249.11, subdivision (c), of the Health and Safety Code, the term "any detectable amount" means a level detected using a method of analysis referred to in this section. For purposes of this section, "method of analysis" refers to the method of detection or detection and calculation for a listed chemical in a specific medium, including, but not limited to, water, air, food, or soil, and shall include methods and procedures concerning the number of samples and the frequency and site of sampling that are specific for the listed chemical in question.

(b) Where the California Department of Health Services, the California Department of Food and Agriculture, the Air Resources Board, a local air pollution control district, the State Water Resources Control Board, or a Regional Water Quality Control Board has adopted or employs a method of analysis for a listed chemical in a specific medium, such method shall be the method of analysis for that chemical in that medium. Where more than one method of analysis has been so adopted or is so employed, each may be utilized as the method of analysis.

(c) Where no state or local agency identified in subdivision (b) has adopted or employs a method of analysis, a method of analysis for a listed chemical in a specific medium adopted or employed by a federal agency shall be the method of analysis for that chemical in that medium. When more than one method of analysis has been so adopted or is so employed, each may be utilized as the method of analysis.

(d) Where no regulatory agency identified in subdivision (b) or (c) has adopted or employs a method of analysis, a method of analysis for a listed chemical in a specific medium which is generally accepted by the scientific community, as evidenced by its publication in compilations by professional and scientific associations or societies, such as the Association of Official Analytical Chemists, or in peer-reviewed technical journals

published by such associations or societies, such method shall be the method of analysis for that chemical in that medium. When more than one method of analysis is generally accepted, each may be utilized as the method of analysis.

(e) Where no method of analysis as described in subsections (b) or (c) has been adopted or is employed, or is generally accepted by the scientific community as described in subsection (d), and a scientifically valid method of analysis has been developed for a listed chemical in a specific medium, such method shall be the method of analysis for that chemical in that medium. Where more than one method of analysis has been developed for a chemical in a specific medium, each may be utilized as the method of analysis.

(f) In performing an analysis to determine the concentration of a chemical known to the state to cause cancer or reproductive toxicity in a given medium, generally accepted standards and practice for sampling, collection, storage, preparation, chemical analysis, statistical analysis of data, interpretation of results and modeling shall be observed.

(g) For purposes of Health and Safety Code Sections 25249.5 and 25249.6, no discharge, release or exposure occurs unless a listed chemical is detectable as provided in this section.

NOTE: Authority cited: Sections 50.7 and 142.3, Labor Code. Reference: Sections 50.7 and 142.3, Labor Code; Sections 25249.6, 25249.7, 25249.8, 25249.10, 25249.11, 25249.12 and 25249.13, Health and Safety Code; and California Lab. Federation v. Occupational Safety and Health Stds. Bd. (1990) 221 Cal.App.3d 1547 [271 Cal. Rptr. 310].

HISTORY

1. New appendix E filed 5-31-91 as an emergency; operative 5-31-91 (Register 91, No. 33). A Certificate of Compliance must be transmitted to OAL by 9-30-91 or emergency appendix E language will be repealed by operation of law on the following day.
2. Amendment of section filed 9-30-91 as an emergency; operative 9-30-91 (Register 92, No. 2). A Certificate of Compliance must be transmitted to OAL 1-28-92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 9-30-91 order transmitted to OAL 11-22-91 and filed 12-17-91 (Register 92, No. 12).
4. Editorial correction of History 3 and 4 (Register 94, No. 50).
5. Editorial correction of #12502 and #12601 (c)(1)(C) (Register 95, No. 24).