

Environmental Protection Agency

§ 350.40

money expended by him in developing the information; (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

Novelty and prior art. A trade secret may be a device or process which is patentable; but it need not be that. It may be a device or process which is clearly anticipated in the prior art or one which is merely a mechanical improvement that a good mechanic can make. Novelty and invention are not requisite for a trade secret as they are for patentability. These requirements are essential to patentability because a patent protects against unlicensed use of the patented device or process even by one who discovers it properly through independent research. The patent monopoly is a reward to the inventor. But such is not the case with a trade secret. Its protection is not based on a policy of rewarding or otherwise encouraging the development of secret processes or devices. The protection is merely against breach of faith and reprehensible means of learning another's secret. For this limited protection it is not appropriate to require also the kind of novelty and invention which is a requisite of patentability. The nature of the secret is, however, an important factor in determining the kind of relief that is appropriate against one who is subject to liability under the rule stated in this section. Thus, if the secret consists of a device or process which is a novel invention, one who acquires the secret wrongfully is ordinarily enjoined from further use of it and is required to account for the profits derived from his past use. If, on the other hand, the secret consists of mechanical improvements that a good mechanic can make without resort to the secret, the wrongdoer's liability may be limited to damages, and an injunction against future use of the improvements made with the aid of the secret may be inappropriate.

Subpart B—Disclosure of Trade Secret Information to Health Professionals

§ 350.40 Disclosure to health professionals.

(a) *Definitions. Medical emergency* means any unforeseen condition which a health professional would judge to require urgent and unscheduled medical attention. Such a condition is one which results in sudden and/or serious symptom(s) constituting a threat to a person's physical or psychological well-being and which requires immediate medical attention to prevent possible deterioration, disability, or death.

(b) The specific chemical identity, including the chemical name of a haz-

ardous chemical, extremely hazardous substance, or a toxic chemical, is made available to health professionals, in accordance with the applicable provisions of this section.

(c) *Diagnosis or Treatment by Health Professionals in Non-Emergency Situations.* (1) An owner or operator of a facility which is subject to the requirements of sections 311, 312, and 313, shall, upon request, provide the specific chemical identity, if known, of a hazardous chemical, extremely hazardous substance, or a toxic chemical to a health professional if:

(i) The request is in writing;

(ii) The request describes why the health professional has a reasonable basis to suspect that:

(A) The specific chemical identity is needed for purposes of diagnosis or treatment of an individual,

(B) The individual or individuals being diagnosed or treated have been exposed to the chemical concerned, and

(C) Knowledge of the specific chemical identity of such chemical will assist in diagnosis or treatment.

(iii) The request contains a confidentiality agreement which includes:

(A) A description of the procedures to be used to maintain the confidentiality of the disclosed information; and

(B) A statement by the health professional that he will not use the information for any purpose other than the health needs asserted in the statement of need authorized in paragraph (c)(1)(ii) of this section and will not release the information under any circumstances, except as authorized by the terms of the confidentiality agreement or by the owner or operator of the facility providing such information.

(iv) The request includes a certification signed by the health professional stating that the information contained in the statement of need is true.

(2) Following receipt of a written request, the facility owner or operator to whom such request is made shall provide the requested information to the health professional promptly.

(d) *Preventive Measures and Treatment by Local Health Professionals.* (1) An owner or operator of a facility subject to the requirements of sections 311, 312,

or 313 shall provide the specific chemical identity, if known, of a hazardous chemical, an extremely hazardous substance, or a toxic chemical to any health professional (such as a physician, toxicologist, epidemiologist, or nurse) if:

(i) The requester is a local government employee or a person under contract with the local government;

(ii) The request is in writing;

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

(A) To assess exposure of persons living in a local community to the hazards of the chemical concerned.

(B) To conduct or assess sampling to determine exposure levels of various population groups.

(C) To conduct periodic medical surveillance of exposed population groups.

(D) To provide medical treatment to exposed individuals or population groups.

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

(F) To conduct studies to aid in the identification of chemicals that may reasonably be anticipated to cause an observed health effect.

(iv) The request contains a confidentiality agreement which includes:

(A) A description of the procedures to be used to maintain the confidentiality of the disclosed information; and

(B) A statement by the health professional that he will not use the information for any purpose other than the health needs asserted in the statement of need authorized in paragraph (d)(1)(iii) of this section and will not release the information under any circumstances except as may otherwise be authorized by the terms of such agreement or by the owner or operator of the facility person providing such information.

(v) The request includes a certification signed by the health professional stating that the information contained in the statement of need is true.

(2) Following receipt of a written request, the facility owner or operator to whom such request is made shall promptly provide the requested information to the local health professional.

(e) *Medical Emergency.* (1) An owner or operator of a facility which is subject to the requirements of sections 311, 312, or 313 must provide a copy of a material safety data sheet, an inventory form, or a toxic chemical release form, including the specific chemical identity, if known, of a hazardous chemical, extremely hazardous substance, or a toxic chemical, to any treating physician or nurse who requests such information if the treating physician or nurse determines that:

(i) A medical emergency exists as to the individual or individuals being diagnosed or treated;

(ii) The specific chemical identity of the chemical concerned is necessary for or will assist in emergency or first-aid diagnosis or treatment; and,

(iii) The individual or individuals being diagnosed or treated have been exposed to the chemical concerned.

(2) Owners or operators of facilities must provide the specific chemical identity to the requesting treating physician or nurse immediately following the request, without requiring a written statement of need or a confidentiality agreement in advance.

(3) The owner or operator may require a written statement of need and a written confidentiality agreement as soon as circumstances permit. The written statement of need shall describe in reasonable detail the factors set forth in paragraph (e)(1) of this section. The written confidentiality agreement shall be in accordance with paragraphs (c)(1)(iii) and (f) of this section.

(f) *Confidentiality Agreement.* (1) The confidentiality agreement authorized in paragraphs (c)(1)(iii), (d)(1)(iv) and (e)(3) of this section:

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

(ii) May provide for appropriate legal remedies in the event of a breach of the agreement; and

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

(g) Nothing in this regulation is meant to preclude the parties from pursuing any non-contractual remedies to the extent permitted by law, or from pursuing the enforcement remedy provided in section 325(e) of Title III.

(h) The health professional receiving the trade secret information may disclose it to EPA only under the following circumstances: The health professional must believe that such disclosure is necessary in order to learn from the Agency additional information about the chemical necessary to assist him in carrying out the responsibilities set forth in paragraphs (c), (d), and (e) of this section. Such information comprises facts regarding adverse health and environmental effects.

PART 355—EMERGENCY PLANNING AND NOTIFICATION

Sec.

- 355.10 Purpose.
- 355.20 Definitions.
- 355.30 Emergency planning.
- 355.40 Emergency release notification.
- 355.50 Penalties.

APPENDIX A TO PART 355—THE LIST OF EXTREMELY HAZARDOUS SUBSTANCES AND THEIR THRESHOLD PLANNING QUANTITIES (ALPHABETICAL ORDER)

APPENDIX B TO PART 355—THE LIST OF EXTREMELY HAZARDOUS SUBSTANCES AND THEIR THRESHOLD PLANNING QUANTITIES (CAS NUMBER ORDER)

AUTHORITY: 42 U.S.C. 11002, 11004, and 11048.

SOURCE: 52 FR 13395, Apr. 22, 1987, unless otherwise noted.

§ 355.10 Purpose.

This regulation establishes the list of extremely hazardous substances, threshold planning quantities, and facility notification responsibilities necessary for the development and implementation of State and local emergency response plans.

§ 355.20 Definitions.

Act means the Superfund Amendments and Reauthorization Act of 1986.

CERCLA means the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended.

CERCLA Hazardous Substance means a substance on the list defined in section 101(14) of CERCLA.

NOTE: Listed CERCLA hazardous substances appear in table 302.4 of 40 CFR part 302.

Chief Executive Officer of the tribe means the person who is recognized by the Bureau of Indian Affairs as the

chief elected administrative officer of the tribe.

Commission means the emergency response commission for the State in which the facility is located except where the facility is located in Indian Country, in which case, *commission* means the emergency response commission for the tribe under whose jurisdiction the facility is located. In absence of an emergency response commission, the Governor and the chief executive officer, respectively, shall be the commission. Where there is a cooperative agreement between a State and a Tribe, the commission shall be the entity identified in the agreement.

Committee or Local emergency planning committee means the local emergency planning committee appointed by the emergency response commission.

Environment includes water, air, and land and the interrelationship which exists among and between water, air, and land and all living things.

Extremely hazardous substance means a substance listed in appendices A and B of this part.

Facility means all buildings, equipment, structure, and other stationary items that are located on a single site or on contiguous or adjacent sites and which are owned or operated by the same person (or by any person which controls, is controlled by, or under common control with, such person). *Facility* shall include manmade structures in which chemicals are purposefully placed or removed through human means such that it functions as a containment structure for human use. For purposes of emergency release notification, the term includes motor vehicles, rolling stock, and aircraft.

Hazardous chemical means any hazardous chemical as defined under §1910.1200(c) of Title 29 of the Code of Federal Regulations, except that such term does not include the following substances:

- (1) Any food, food additive, color additive, drug, or cosmetic regulated by the Food and Drug Administration.
- (2) Any substance present as a solid in any manufactured item to the extent exposure to the substance does not occur under normal conditions of use.
- (3) Any substance to the extent it is used for personal, family, or household