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Title 22@ Social Security

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Division 4.5@ Environmental Health Standards for the Management of Hazardous Waste

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Chapter 54@ Green Chemistry Hazard Traits, Toxicological and Environmental Endpoints and Other Relevant Data

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Article 2@ Toxicological Hazard Traits - Carcinogenicity, Developmental Toxicity, and Reproductive Toxicity

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Section 69402.6@ Evidence for Reproductive Toxicity Hazard Trait

## **69402.6 Evidence for Reproductive Toxicity Hazard Trait**

### **(a)**

Each of the following constitutes strong evidence of reproductive toxicity for a given chemical substance: (1) Identification as known to the state to cause reproductive toxicity with male or female reproductive toxicity or both denoted as an endpoint in Title 27, California Code of Regulations, section 27001. (2) Meeting the National Toxicology Program criteria as having clear or sufficient evidence of adverse effects for reproductive toxicity. (3) Meeting the criteria for being classified as Category 1 for known or presumed effects on human reproduction or on development based on male or female reproductive toxicity data under the United Nations' Globally Harmonized System for Classification and Labeling of Chemicals. (4) Identification as a known or potential male or female reproductive toxicant or both or having the capacity to cause reproductive toxicity in a report by the National Academy of Sciences' National Research Council or Institute of Medicine. (5) Identification in the National Institute for Occupational Safety and Health ("NIOSH") Pocket Guide to Chemical Hazards with having reproductive organs as the target organ or as having sterility or other reproductive effects. (6) Recognition as a reproductive toxicant by an authoritative organization.

### **(1)**

Identification as known to the state to cause reproductive toxicity with male or female reproductive toxicity or both denoted as an endpoint in Title 27, California Code of

Regulations, section 27001.

**(2)**

Meeting the National Toxicology Program criteria as having clear or sufficient evidence of adverse effects for reproductive toxicity.

**(3)**

Meeting the criteria for being classified as Category 1 for known or presumed effects on human reproduction or on development based on male or female reproductive toxicity data under the United Nations' Globally Harmonized System for Classification and Labeling of Chemicals.

**(4)**

Identification as a known or potential male or female reproductive toxicant or both or having the capacity to cause reproductive toxicity in a report by the National Academy of Sciences' National Research Council or Institute of Medicine.

**(5)**

Identification in the National Institute for Occupational Safety and Health ("NIOSH") Pocket Guide to Chemical Hazards with having reproductive organs as the target organ or as having sterility or other reproductive effects.

**(6)**

Recognition as a reproductive toxicant by an authoritative organization.

**(b)**

Each of the following constitutes suggestive evidence of reproductive toxicity for a given chemical substance: (1) Meeting the National Toxicology Program criteria as having some or limited evidence of adverse effects for reproductive toxicity. (2) Recognition as a suspected reproductive toxicant by an authoritative organization. (3) Strong evidence for the Genotoxicity Hazard Trait pursuant to Article 3 subsection 69403.5 of this Chapter or the Endocrine Toxicity Hazard Trait

pursuant to Article 3 subsection 69403.3 of this Chapter with mechanisms of genotoxicity or endocrine toxicity likely to be involved in reproductive toxicity. (4) Supportive studies, as defined by the National Toxicology Program, indicating possible male or female reproductive toxicity. (5) Mechanistic evidence that is suggestive of reproductive toxicity potential, from cell-based, tissue-based or whole organism-based assays showing perturbations of known physiological, biochemical or other pathways involved in reproductive toxicity. (6) Strong indications of reproductive toxicity from structure activity relationships, including but not limited to those from Quantitative Structure Activity Relationship models.

**(1)**

Meeting the National Toxicology Program criteria as having some or limited evidence of adverse effects for reproductive toxicity.

**(2)**

Recognition as a suspected reproductive toxicant by an authoritative organization.

**(3)**

Strong evidence for the Genotoxicity Hazard Trait pursuant to Article 3 subsection 69403.5 of this Chapter or the Endocrine Toxicity Hazard Trait pursuant to Article 3 subsection 69403.3 of this Chapter with mechanisms of genotoxicity or endocrine toxicity likely to be involved in reproductive toxicity.

**(4)**

Supportive studies, as defined by the National Toxicology Program, indicating possible male or female reproductive toxicity.

**(5)**

Mechanistic evidence that is suggestive of reproductive toxicity potential, from cell-based, tissue-based or whole organism-based assays showing perturbations of known physiological, biochemical or other pathways involved in reproductive toxicity.

**(6)**

Strong indications of reproductive toxicity from structure activity relationships, including but not limited to those from Quantitative Structure Activity Relationship models.