PLAINTIFF'S EXHIBIT
KM-359

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(p) *Substantial personal injury or illness.* This term means any illness or injury of a significant nature. It need not be severe or serious. What is excluded by the word "substantial" is a wholly insignificant or negligible injury or illness.

(q) *Proximate result.* A proximate result is one that follows in the course of events without an unforeseeable, intervening, independent cause.

(r) *Reasonably foreseeable handling or use.* This includes the reasonably forseeable accidental handling or use, not only by the purchaser or intended user of the product, but by all others in a household, especially children.

(s) *Banned hazardous substance.* The term "banned hazardous substance" means:

(1) Any toy or other article intended for use by children that is a hazardous substance within the meaning of section 2(f)(1) of the act or any regulation in this part, or bears or contains such a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted; or

(2) Substances other than those defined in subparagraph (1) of this paragraph that are intended or packaged in a form suitable for use in the household and that the Commissioner finds and classifies by regulation as being so hazardous in nature that the objective of protecting the public health and safety can be adequately served only by keeping such substance when so intended or packaged out of the channels of interstate commerce.

§ 191.2 Human experience with hazardous substances.

Reliable data on human experience with any substance should be taken into account in determining whether an article is a "hazardous substance" within the meaning of the act, and when such data give reliable results different from results with animal data, the human experience takes precedence. Experience may show that an article is more or less toxic, irritant, or corrosive to man than to test animals. Experience may also show other factors that are important in determining the degree of hazard to humans represented by the substance. For example, that radiator antifreeze is likely to be stored in the household or garage and likely to be ingested in significant quantities by some persons. Experience also indicates that a particular substance in liquid form is more likely to be ingested than is the same substance in a paste or a solid and that an aerosol is more likely to get into the eyes and the nasal passages than is a liquid.

§ 191.3 Hazardous mixtures.

For a mixture of substances, the determination of whether such mixture is "hazardous" as defined in section 2(f) of the act should be based on the physical, chemical, and pharmacological characteristics of the mixture. A mixture of substances may therefore be less hazardous or more hazardous than its components because of synergistic or antagonistic reactions. It may not be possible to reach a fully satisfactory decision concerning the toxic, irritant, corrosive, flammable, sensitizing, or pressure-generating properties of a substance from what is known about its components or ingredients. It is prudent to test the mixture itself.

§ 191.4 [Reserved]

*§ 191.5 Products declared to be hazardous substances under section 3(a) of the act.

(a) The Commissioner finds that the following articles are hazardous substances within the meaning of the act because they are capable of causing substantial personal injury or substantial illness during or as a proximate result of any customary or reasonable foreseeable handling or use:

(1) Charcoal briquettes and other forms of charcoal in containers for retail sale and intended for cooking or heating. *

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§ 191.6 Listing of "strong sensitizer" substances.

The Commissioner of Food and Drugs, having considered the frequency of occurrence and the severity of reactions, finds the following substances to have a significant potential for causing hypersensitivity, and therefore they meet the definition for "strong sensitizer" as given in section 2(k) of the act.

(a) Paraphenylenediamine and products containing it.

(b) Powered orris root and products containing it.

(c) Epoxy resins systems containing in any concentration ethylenediamine, diethylenetriamine, and diglycidyl ethers of molecular weight of less than 200.

(d) Formaldehyde and products containing 1 percent or more of formaldehyde.

(e) Oil of bergamot and products containing 2 percent or more of oil of bergamot.

§ 191.7 Products requiring special labeling under section 3(b) of the act.

(a) Human experience as reported in the scientific literature and to the Poison Control Centers and the National Clearing House for Poison Control Centers, together with opinions of informed medical experts, establishes that the following substances are hazardous:

* (1) [Deleted] *

(2) Diethylene glycol including mixtures containing 10 percent or more by weight of diethylene glycol.

(3) Ethylene glycol including mixtures containing 10 percent or more by weight of ethylene glycol.

(4) Products containing 5 percent or more, by weight, of benzene (also known as benzol) and products containing 10 percent or more, by weight, of toluene (also known as toluol), xylene (also known as xylol), or petroleum distillates such as kerosine, mineral seal oil, naphtha, gasoline, mineral spirits, stoddard solvent, and related petroleum distillates.

(5) Methyl alcohol including mixtures containing 4 percent or more by weight of methyl alcohol.

(6) Turpentine including gum turpentine, gum spirits of turpentine, steam-distilled wood turpentine, sulfate wood turpentine and, destructively distilled wood turpentine and mixtures containing 10 percent or more by weight of such turpentine.

(b) The Commissioner finds that these substances present special hazards and that the labeling required by section 2(p)(1) of the act is not adequate for the protection of the public health. Under section 3(b) of the act the following specific label statements are deemed necessary to supplement the labeling required by section 2(p)(1) of the act:

* (1) [Deleted] *

(2) *Methyl alcohol.* Because death and blindness might result from the ingestion of methyl alcohol, the label for this substance (including mixtures) within the precentages specified in paragraph (a)(5) of this section shall include the signal word "danger," the additional word "poison," and the skull and crossbones symbol. The statement of hazard shall include "Vapor harmful" and "May be fatal or cause blindness if swallowed." The label shall also bear the statement "Cannot be made nonpoisonous."

(3) *Benzene, toluene, xylene, petroleum distillates.* (i) Because inhalation of the vapors of products containing 5 percent or more, by weight, of benzene may cause blood dyscrasias, such products shall be labeled with the signal word "danger," the statement of hazard "Vapor harmful," and the word "poison," and the skull and crossbones symbol. If the product contains 10 percent or more, by weight, of benzene, it shall bear the additional statement of hazard "Harmful or fatal if swallowed" and the additional statements "If swallowed, do not induce vomiting. Call physician immediately."

(ii) Because products containing 10 percent or more, by weight, of toluene, xylene, or any of the other substances listed in paragraph (a)(4) of this section may be aspirated into the lungs, with resulting chemical pneumonitis, pneumonia, and pulmonary edema, such products shall be labeled with the signal word "danger," the statement of hazard "Harmful or fatal if swallowed," and the statements "If swallowed, do not induce vomiting. Call physician immediately."

(iii) Because inhalation of the vapor of products containing 10 percent or more, by weight, of toluene or xylene may cause systemic injury, such products shall bear the statement of hazard "Vapor harmful" in addition to the statements prescribed in subdivision (ii) of this subparagraph.

(4) *Ethylene glycol and diethylene glycol.* Because these substances (including mixtures) within the percentages specified above are commonly marketed, stored, and used in a manner increasing the possibility of accidental ingestion, the

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signal word "warning" is specified. In addition, for ethylene glycol the statement "Harmful or fatal if swallowed" and for diethylene glycol the statement "Harmful if swallowed" are required.

(5) *Turpentine.* Because products containing 10 percent or more, by weight, of turpentine, in addition to oral toxicity resulting in systemic poisoning, may be aspirated into the lungs, with resulting chemical pneumonitis, pneumonia, and pulmonary edema, such products shall be labeled with the signal word "danger" and the statement of hazard "Harmful or fatal if swallowed."

*(6) Charcoal briquettes and other forms of charcoal in containers for retail sale and intended for cooking or heating.

(i) Because inhalation of the carbon monoxide produced by burning charcoal indoors or in confined areas may cause serious injury or death, containers of such products shall bear the following borderlined statement:

> WARNING: Do not use for Indoor Heating or Cooking Unless Ventilation Is Provided for Exhausting Fumes to Outside. Toxic Fumes May Accumulate and Cause Death.

(ii) For bags of charcoal the statement specified in subdivision (i) of this subparagraph shall appear within a heavy borderline in a color sharply contrasting to that of the background, on both front and back panels in the upper 25 percent of the panels of the bag at least 2 inches below the seam, and at least 1 inch above any reading material or design elements in type size as follows: The signal word "WARNING" shall appear in capital letters at least three-eighths inch in height; the remaining text of the aforementioned warning statement shall be printed in letters at least three-sixteenths inch in height. *

TESTING PROCEDURES FOR HAZARDOUS SUBSTANCES

§ 191.8 Labeling of fire extinguishers.

When a substance or mixture of substances labeled for use in or as a fire extinguisher produces substances that are toxic within the meaning of § 191.1 (e) and (f) when used according to label directions to extinguish a fire, the containers for such substances shall bear the following labeling:

(a) When substances are produced which meet the definition of highly toxic within the meaning of § 191.1(e) the signal word "Danger" and the statement of hazard, "Poisonous gases formed when used to extinguish flame or on contact with heat" are specified.

(b) When substances are produced which meet the definition of toxic within the meaning of § 191.1(f), the signal word "Caution" or "Warning," and the statement of hazard, "Dangerous gas formed when used to extinguish flame or on contact with heat" are specified.

(c) Regardless of whether paragraph (a) or (b) of this section applies, any substance or mixture of substances labeled for use as a fire extinguisher that if applied to an electrical fire would subject the user to the likelihood of electrical shock shall be conspicuously labeled "Caution: Do not use on electrical wires."

These statements shall be in addition to any other that may be required under the act or this section. All such substances or mixtures of substances shall also bear the additional statements: "Use in an enclosed place may be fatal" and "Do not enter area until well ventilated and all odor of chemical has disappeared."

§ 191.9 Banned hazardous substances.

(a) Under the authority of section 2 (q)(1)(B) of the the act, the Commissioner declares as banned hazardous substances the following articles because they possess such a degree of hazard that adequate cautionary labeling cannot be written and the public health and safety can be served only by keeping such articles out of interstate commerce:

(1) Mixtures that are intended primarily for application to interior masonry walls, floors, etc., as a water repellant treatment and that are "extremely flammable" within the meaning of section 2(l) of the act.

(2) Carbon tetrachloride and mixtures containing it (including carbon tetrachloride and mixtures containing it used in fire extinguishers), excluding unavoidable manufacturing residues of carbon tetrachloride in other chemicals that under reasonably foreseeable conditions of use do not result in an atmospheric concentration of carbon tetrachloride greater than 10 parts per million.

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(9) Porous-tip ink-marking devices are exempt from the labeling requirements of section 2(p)(1) of the act and § 191.7(b)(3) (ii) and (iii) and (4) insofar as such requirements would be necessary because the ink contained therein is a toxic substance as defined in § 191.1 (f)(1); and/or because the ink contains 10 percent or more by weight of toluene (also known as toluol), xylene (also known as xylol), or petroleum distillates as defined in § 191.7(a)(4); and/or because the ink contains 10 percent or more by weight of ethylene glycol: *Provided*, That:

(i) The porous-tip ink-marking devices are of such construction that the ink is held within the device by an absorbent material so that there is no free liquid within the device, and under any reasonably foreseeable conditions of manipulation and use including reasonably foreseeable abuse by children, the ink will emerge only through the porous writing nib of the device; and

(ii) (*a*) The device has a capacity of not more than 10 grams of ink, and the ink, when tested by methods described in § 191.1(f)(1), has an LD_{50} single oral dose of not less than 2.5 grams per kilogram of body weight of the test animal; or

(*b*) The device has a capacity of not more than 12 grams of ink and the ink, when tested by methods described in § 191.1(f)(1), has an LD_{50} single oral dose of not less than 3.0 grams per kilogram of body weight of the test animal.

(10) Viscous nitrocellulose-base adhesives containing more than 4 percent methyl alcohol by weight are exempted from the label statement "Cannot be made nonpoisonous" required by § 191.7(b)(2): *Provided*, That:

(i) The total amount of methyl alcohol, by weight, in the product does not exceed 15 percent; and

(ii) The contents of any container does not exceed 2 fluid ounces.

(11) Packages containing polishing or cleaning products which consist of a carrier of solid particulate or fibrous composition and which contain toluene (also known as toluol), xylene (also known as xylol), or petroleum distillates in the concentrations described in § 191.7 (a)(4) are exempt from the labeling requirements of § 191.7(b)(3)(ii), provided that such toluene, xylene, or petroleum distillate is fully absorbed by the solid, semisolid, or fibrous carrier and cannot be expressed therefrom with any reasonably foreseeable conditions of manipulation.

(12) Containers of dry ink intended to be used as a liquid ink after the addition of water are exempt from the labeling requirements of section 2(p)(1) of the act and § 191.7(b)(4), insofar as such requirements would be necessary because the dried ink contained therein is a toxic substance as defined in § 191.1(f)(1) and/or because the ink contains 10 percent or more ethylene glycol as defined in § 191.7(a)(3): *Provided*, That:

(i) When tested by the method described in § 191.1(f)(1), the dry ink concentrate does not have an LD_{50}[1] single oral dose of less than 1 gram per kilogram of body weight of the test animal.

(ii) The dry ink concentrate enclosed in a single container does not weigh more than 75 milligrams.

(iii) The dry ink concentrate does not contain over 15 percent by weight of ethylene gycol.

(13) Containers of liquid and semisolid substances such as viscous-type paints, varnishes, lacquers, roof coatings, rubber vulcanizing preparations, floor covering adhesives, glazing compounds, and other viscous products containing toluene (also known as toluol), xylene (also known as xylol), or petroleum distillates in concentrations described in § 191.7(a)(4) are exempt from the labeling requirements of § 191.7(b)(3)(ii) insofar as that paragraph applies to such toluene, xylene, or petroleum distillates: *Provided*, That the viscosity of the substance or of any liquid that may separate or be present in the container is not less than 100 Saybolt Universal Seconds at 100° F.

(14) Customer-owned portable containers that are filled by retail vendors with gasoline, kerosene (kerosine), or other petroleum distillates are exempt from the provision of section 2(p)(1)(A) of the act, which requires that the name and place of business of the manufacturer, distributor, packer, or seller appear on the label of such containers, provided that all the other label statements required by section 2(p)(1) of the act and § 191.7(b)(3) appear on the labels of containers of the substances named in this subparagraph.

[1] Lethal dose, median (lethal for 50 percent or more of test group).