FDA
TALK PAPER

Food and Drug Administration
U S Department of Health and Human Services
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LATEX LABELING REQUIRED FOR MEDICAL DEVICES

In response to reports of allergic reactions to some medical devices, the Food and Drug Administration is requiring all medical devices containing latex to be labeled as such and to carry a caution that latex can cause allergic reactions

Devices that contain natural rubber latex will be required to carry a statement on the label which says, "Caution· This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions " Medical device packaging that contains latex will be required to carry a similar statement on the label Products and packaging that contain dry natural rubber will have to be identified as containing dry natural rubber

The new requirements, published today in the Federal Register as a final regulation, will help protect people who are allergic to latex by enabling them to easily identify medical devices that contain latex and avoid contact with them

Over the past decade, FDA has received more than 1,700 reports of severe allergic reactions, including 16 deaths, related to medical devices containing latex The deaths all occurred in 1989 among children with spina bifida They were caused by a reaction to latex cuffs used on the tip of barium enema catheters The manufacturer voluntarily recalled all the enema tips on the market and started using tips with silicone cuffs instead

Allergic reactions have been reported to a wide range of medical devices that contain latex, including latex surgical gloves, adhesive bandages, intravenous catheters, and anesthesia equipment FDA sponsored an international conference on latex sensitivity in 1992 to determine the cause and extent of the problem and explore ways to address it

For the general public, the risk of an allergic reaction to latex is estimated to be less than 1 percent But because of constant exposure to latex, two groups are at greater risk--health-care workers and children with spina bifida and other conditions involving multiple surgical procedures

FDA is also requiring that all "hypoallergenic" claims on medical devices be removed because they incorrectly imply that the devices may be safely used by people sensitive to latex Such claims are currently found on many medical devices that contain reduced levels of latex protein However, these products may still cause allergic reactions in people who are latex sensitive

Manufacturers have one year -- until Sept 30, 1998 --, to comply with the new law The regulation does not apply to latex containing medical devices that do not come in contact with people ####

FDA HOME PAGE

FDA Final Rule

' significant regulatory action ' under Executive Order 12866, (2) is not a "significant rule' under DOT Regulatory Policies and Procedures (44 FR 11034 February 26, 1979), and (3) will not have a significant economic impact positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act A copy of the final evaluation prepared for this action is contained in the rules docket A copy of it may be obtained by contacting the rules docket at the location provided under the caption **ADDRESSES**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft Aviation safety, Incorporation by reference, Safety

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows

PART 39—AIRWORTHINESS DIRECTIVES

1 The authority citation for part 39 continues to read as follows

Authority 49 USC 106(g), 40113 44701

§39 13 [Amended]

2 Section 39 13 is amended by adding a new airworthiness directive (AD) to read as follows

97-20-11 Socata—Groupe Aerospatiale Amendment 39-10148 Docket No 97-CE-15-AD

Applicability Model TBM 700 airplanes (serial numbers 1 through 109) certificated in any category that do not have the main landing gear (MLG) inboard doors and the door locking control mechanism removed (MOD 70-065-32) in accordance with the Technical Instruction of Modification OPT70 KO59-32, dated December 1995 as referenced in Socata Service Bulletin (SB) 70-073 Amdt 1 dated June 1996

Note 1 This AD applies to each airplane identified in the preceding applicability provision regardless of whether it has been modified altered or repaired in the area subject to the requirements of this AD For airplanes that have been modified altered or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD The request should include an assessment of the effect of the modification alteration, or repair on the unsafe condition addressed by this AD and, if the unsafe condition has not been eliminated the request should include specific proposed actions to address it

Compliance Required within the next 100 hours time-in-service after the effective date of this AD or within the next 6 calendar months after the effective date of this AD, whichever occurs first unless already accomplished

To prevent the MLG from failing to extend because of corroded MLG inboard locking hinges which could result in loss of control of the airplane during landing operations accomplish the following

(a) Remove the MLG inboard doors and the door locking control mechanism (MOD 70-065-32) in accordance with the Technical Instruction of Modification OPT70 KO59-32 - dated December 1995, as referenced in Socata SB 70-073, Amdt 1, dated June 1996

(b) As of the effective date of this AD no person may undo MOD 70-065-32 on any affected airplane, by reinstalling the MLG inboard doors and the door locking control mechanism

(c) Special flight permits may be issued in accordance with sections 21 197 and 21 199 of the Federal Aviation Regulations (14 CFR 21 197 and 21 199) to operate the airplane to a location where the requirements of this AD can be accomplished

(d) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager Small Airplane Directorate FAA 1201 Walnut, suite 900, Kansas City Missouri 64106 The request shall be forwarded through an appropriate FAA Maintenance Inspector who may add comments and then send it to the Manager Small Airplane Directorate

Note 2 Information concerning the existence of approved alternative methods of compliance with this AD if any, may be obtained from the Small Airplane Directorate

(e) The removal required by this AD shall be done in accordance with the Technical Instruction of Modification OPT70 KO59-32 dated December 1995 as referenced in Socata Service Bulletin 70-073, Amdt 1, dated June 1996 This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U S C 552(a) and 1 CFR part 51 Copies may be obtained from Socata—Groupe Aerospatiale Socata Product Support, Aeroport Tarbes-Ossun-Lourdes B P 930, 65009 Tarbes Cedex France, or the Product Support Manager Socata—Groupe Aerospatiale North Perry Airport 7501 Pembroke Road, Pembroke Pines Florida 33023 Copies may be inspected at the FAA Central Region Office of the Regional Counsel Room 1558, 601 E 12th Street Kansas City Missouri, or at the Office of the Federal Register 800 North Capitol Street NW suite 700 Washington, DC

(f) This amendment (39-10148) becomes effective on November 13, 1997

Issued in Kansas City Missouri on September 24 1997

Henry A Armstrong,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service

[FR Doc 97-25832 Filed 9-29-97 8 45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No 96N-0119]

21 CFR Part 801

Natural Rubber-Containing Medical Devices; User Labeling

AGENCY: Food and Drug Administration, HHS

ACTION: Final rule

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule requiring labeling statements on medical devices, including device packaging containing natural rubber that contacts humans The rule requires labeling of medical devices containing natural rubber latex that contacts humans to state "Caution This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions ", labeling of medical devices containing dry natural rubber that contacts humans to state "This Product Contains Dry Natural Rubber ", labeling of medical devices containing natural rubber latex in their packaging that contacts humans to state 'Caution The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions ", labeling of medical devices containing dry natural rubber in their packaging that contacts humans to state "The Packaging of This Product Contains Dry Natural Rubber ", and that the claim of hypoallergenicity be removed from the labeling of medical devices that contain natural rubber These requirements are being established in response to numerous reports of severe allergic reactions and deaths related to a wide range of medical devices containing natural rubber

EFFECTIVE DATE: This final rule is effective September 30, 1998

FOR FURTHER INFORMATION CONTACT: Donald E Marlowe, Center for Devices and Radiological Health (HFZ-100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20850, 301-443-2444, FAX 301-443-2296

SUPPLEMENTARY INFORMATION:

I Background

Natural latex is a milky fluid obtained in commercial quantities primarily from the *Heavea brasiliensis* (rubber) tree There is often confusion concerning the terminology used to describe the raw agricultural materials derived from rubber-producing plants, products made from various intermediate forms of the

raw agricultural material (e g , natural rubber latex dry natural rubber) formulations of synthetic latex and synthetic rubber to which natural rubber has been added and synthetic rubber and synthetic latex formulations that do not contain natural rubber

'Natural latex,' for the purposes of this rule, is defined as a milky fluid that consists of extremely small particles of rubber obtained from plants, principally from the *H brasiliensis* (rubber) tree, dispersed in an aqueous medium It contains a variety of naturally occurring substances, including cis-1 4-polyisoprene in a colloidal suspension (Ref 1) and plant proteins, which are believed to be the primary allergen (Refs 2 3, and 4)

"Natural rubber,' for the purposes of this rule, includes all materials made from or containing natural latex Products that contain natural rubber are made using two commonly employed manufacturing processes, the natural rubber latex (NRL) process and the dry natural rubber (DNR) process

The NRL manufacturing process involves the use of natural latex in a concentrated colloidal suspension Products are formed from natural rubber latex by dipping, extruding, or coating, and are typically referred to as containing or made of "natural rubber latex ' Examples of products that may contain natural rubber latex include medical gloves, catheters, tracheostomy ubes, and condoms

The DNR manufacturing process involves the use of coagulated natural latex in the form of dried or milled sheets Products are formed from dry natural rubber by compression molding, extrusion, or by converting the sheets into a solution for dipping These products are typically referred to as containing or made of dry natural rubber or 'crepe" rubber Examples of products that may contain dry natural rubber include syringe plungers, vial stoppers and injection ports on intravascular tubing

The phrase "contains natural rubber, as used herein, also includes products described as made of "synthetic latex or "synthetic rubber ' that include natural rubber in their formulations This rule does not apply to products made from synthetic latex or synthetic rubber that do not include natural rubber in their formulations

FDA has noted an increase in the number of reports submitted to its medical device reporting system regarding sensitivity to natural latex proteins contained in medical devices, including deaths following barium enemas These deaths were associated with anaphylactic reactions to the natural rubber latex cuff on the tip of barium enema catheters Scientific studies and case reports have documented sensitivity to natural latex proteins found in a wide range of medical devices (see Refs 2 through 23)

Based upon this information, the agency published a proposed rule on June 24, 1996 (61 FR 32618), to require labeling statements on medical devices containing natural rubber that contact humans This final rule is based upon comments submitted in response to the June 24, 1996 proposed rule

II Highlights of the Final Rule

A Natural Rubber-Containing Devices, Labeling

FDA is requiring the labeling for medical devices containing natural rubber that contacts humans to include a statement regarding the presence of natural rubber The agency is issuing this rule because medical devices composed of natural rubber, or which contain components formulated from natural rubber, may pose a significant health risk to some consumers or health care providers who are sensitized to natural latex proteins A statement in the labeling of medical devices identifying the presence of natural rubber latex is considered to be necessary for the safe and effective use of such devices

"Contacts humans," for the purposes of this rule, means that the natural rubber contained in a medical device is intended to contact or is likely to contact the user or patient This includes contact when the natural rubber containing device is connected to the patient by a liquid path or an enclosed gas path or the natural rubber containing device is powdered and the powder may carry natural latex proteins that may contaminate the environment of the user or patient

The device may bear one or more of four labeling statements depending on the type of natural rubber in the device and depending on whether the natural rubber is in the device itself or in its packaging The reasoning for requiring one or more of four separate statements is discussed more fully in comments 3 and 6 in section III of this document

Medical devices containing rubber produced by the NRL process that contacts humans shall bear labeling with the following statement in bold print "Caution This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions " Representative examples of devices that contain NRL include Cuffed enema/enterolysis catheters, latex condoms (with or without spermicidal lubricant), wound drains, cuffed airways, latex surgical gloves, and latex examination gloves

The agency is also requiring that medical devices containing rubber produced by the DNR process that contacts humans include the following statement in bold print in their labeling 'This Product Contains Dry Natural Rubber " Representative examples of devices that contain DNR include Anesthesia masks, electrode pads, contraceptive diaphragms, crutch pads and tips, wheelchair tires, elastic components of bandages/face masks, syringe plungers, parenteral drug vial stoppers, and intravenous injection ports

The agency is further requiring medical devices having packaging that contains natural rubber that contacts humans bear labeling with one of the following statements in bold print "Caution The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions " or "The Packaging of This Product Contains Dry Natural Rubber ", as appropriate The purpose of such statements is to inform individuals who are sensitive to natural rubber about the presence of natural rubber in the packaging of devices that may be, by themselves, natural rubber-free

B Hypoallergenicity

FDA believes that it is also necessary to prohibit certain labeling statements on medical devices that contain natural rubber FDA believes that the labeling statement "hypoallergenic," traditionally used with respect to medical gloves, cosmetics, and other products produced for individuals with chemical allergies, is interpreted by consumers to mean that the risk of allergic reactions to any component of the device would be minimal This is not the case with devices that contain natural rubber FDA has received reports of allergic reactions to medical gloves labeled as "hypoallergenic "

Use of the "hypoallergenic" label has been based on results of the modified (human) Draize test While this test may be appropriate for detecting sensitization to residual levels of processing chemicals, the test does not detect sensitivity to natural latex proteins

Thus, there is no reasonable assurance that the risk of allergic reactions to products that contain natural rubber, yet have reduced levels of processing chemicals, will be reduced for individuals who are sensitive to natural latex proteins Therefore, the agency believes that the term "hypoallergenic ' on the labeling of a device that contains natural rubber is misleading in that it

incorrectly implies that such device may be used safely by persons sensitive to natural latex proteins For these reasons FDA is requiring that the hypoallergenic claim be removed from he labeling of devices that contain natural rubber

C Effects of This Regulation on Premarket Submission Requirements

FDA will not require a new submission under section 510(k) of the Federal Food, Drug and Cosmetic Act (the act) (21 U S C 360(k)) based upon labeling changes made to comply with this rule provided that no other changes requiring a new 510(k) submission under 21 CFR 807 81 are made to the device Devices subject to an approved premarket approval application, however must submit any change to the device labeling that is required by this rule in the next interim report under 21 CFR 814 39(e) Combination products that have device and drug components but are regulated under drug premarket approval provisions shall indicate the labeling change in a supplement for changes that may be made before FDA approval, as required by 21 CFR 314 70(c) Combination products that have device and biological components, but that are regulated under the biologic premarket approval provisions shall inform the agency of the labeling change in the manner described under 21 CFR 601 12

III Summary of Comments

The agency received 62 comments, all of which supported the principle of natural rubber labeling for the protection of natural rubber sensitive individuals The comments, however differed greatly in their specific approaches

1 A few comments suggested using the term "crepe rubber," instead of "dry rubber, ' and suggested using the term ' synthetic rubber" instead of 'synthetic latex '

The agency agrees that "synthetic rubber" should be used to describe components of certain natural rubber products covered by this regulation and has added that term in the definition of ' natural rubber ' in § 801 437(b) (21 CFR 801 437(b)) Although the agency has discussed the meaning of crepe rubber in the preamble to this regulation, the agency does not agree that the term "crepe rubber ' should be used in place of dry natural rubber ' in the regulation because the agency believes the term ' dry natural rubber' is the term most commonly used to describe rubber manufactured by the DNR process

2 One comment pointed out that there are other sources of natural rubber besides that identified in the preamble of the proposed rule, the *H brasiliensis* tree

The agency agrees and has clarified in the preamble of this regulation that there are other sources of plant-derived natural rubber used in the manufacture of devices that are subject to this rule The preamble notes that the *H brasiliensis* tree is the primary source of commercial natural latex, instead of the only source

3 Several comments claimed that there is no information to suggest that dry natural rubber has caused allergic reactions in individuals sensitive to natural latex proteins therefore dry natural rubber should not be included in the labeling requirement

The agency recognizes that there are lower levels of natural latex proteins in products produced by the dry natural rubber process The agency, however does not agree that there is no information to suggest that dry natural rubber has caused allergic reactions in individuals sensitive to natural latex proteins To the contrary, there are numerous reports that levels of natural latex proteins found in dry rubber can cause allergic reactions (Refs 24 through 27) Accordingly, the agency has concluded that it is in the best interest of the public health to provide labeling information that a product contains dry natural rubber, so that individuals who are sensitive to the levels of natural latex proteins found in dry natural rubber may make an informed decision regarding the use of the product

While the agency believes that persons who may respond to the levels of natural latex proteins found in dry natural rubber need to be informed of the dry rubber content in a device, the agency does not believe that those individuals need to be informed of the health consequences associated with dry natural rubber Because allergy is a dose-response phenomenon, persons who may react to natural latex protein levels found in dry rubber would have already experienced previous allergic reactions to the higher levels of natural latex proteins found in natural rubber latex products (see Ref 28) Therefore, those individuals would generally be aware that dry natural rubber may cause them to suffer an allergic reaction Accordingly, FDA is requiring that products that contain only dry rubber have labeling that informs consumers of the dry rubber content, but is not requiring that such products bear labeling that states the potential health consequences from the use of the product Therefore, FDA is requiring in the final regulation, § 801 437(e), that devices that contain dry natural rubber bear labeling with the following statement "This Product Contains Dry Natural Rubber '

Persons who would not react to the levels of natural latex proteins found in dry rubber, but would react to the higher levels of natural latex proteins found in natural rubber latex products however, may never have been aware of previous allergic reactions (Ref 28) These persons therefore, need to be advised of the potential health consequences of natural rubber latex products Accordingly, FDA is requiring products containing natural rubber latex to carry labeling that states the potential health consequences of such products, as well as a natural rubber latex content statement Therefore, FDA is requiring in the final regulation, § 801 437(d), that devices containing natural rubber latex have labeling with the following statement in bold print "Caution This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions "

This statement is also required if a device contains both natural rubber latex and dry natural rubber that may contact humans In this instance, the single statement will serve to advise a person who may not be aware that natural rubber may cause reactions, and will also advise a person who is aware of his or her sensitivity to natural rubber that the product contains an ingredient that may cause a reaction.

4 Some comments claimed that the applicability of the labeling statement to devices that contain natural rubber "that may directly or indirectly contact humans" is overly broad One comment suggested that the labeling statement be required only on devices that have an "intended use" that may lead to contact with humans Other comments suggested the statement be limited to devices which would directly contact tissues

The agency does not believe that the application of the labeling statement to devices that contain natural rubber "that may directly or indirectly contact humans" is overly broad Latex proteins may elicit an allergic reaction in individuals who are sensitive to natural rubber, even if the proteins are introduced to the individual through an indirect route The agency, however, recognizes that the term "indirect contact' may be interpreted more broadly than the agency intends Therefore, in order to avoid confusion, the agency has modified the regulation to require the labeling statements only if the natural rubber contacts humans The final regulation, § 801 437(b), defines the term "contacts humans" to mean that the natural rubber contained

in a device is intended to contact or is likely to contact the user or patient (e g latex medical gloves or latex enema tips) This includes contact when the device that contains natural rubber is connected to the patient by a liquid path or an enclosed gas path (e g , intervenous administration sets, or blood collection or transfusion tubing with natural rubber injection ports, injection syringes with natural rubber plungers or natural rubber tubing or connector components used in anesthesia or endoscopic insufflator circuits) This also includes contact when the device that contains natural rubber is fully or partially coated with a powder and such powder may carry natural rubber proteins that may contaminate the environment of the user or patient (e g , latex tourniquets) This definition makes it clear that the labeling statement is required on devices that have an intended use that could reasonably be expected to introduce natural latex proteins to humans

5 Several comments suggested that the natural rubber labeling statement be expanded to apply to nonmedical natural rubber latex gloves and other consumer products that contain natural rubber Other comments suggested that medical devices sold over-the-counter (OTC) to the consumer be exempt from the labeling requirements in order to avoid confusion regarding the natural rubber-content of other consumer goods that would not be subject to this labeling regulation

The agency disagrees that the regulation should apply to nonmedical natural rubber latex gloves and other consumer products that contain natural rubber The regulation of such products is beyond the scope of this rule FDA's authority under the act to impose labeling requirements is restricted to products that meet the definition of foods drugs cosmetics, animal drugs, biologics, and devices, as those terms are defined under the act This rule applies to devices as defined under section 201(h) of the act (21 U S C 321(h)) Under section 201(h) of the act a device is

> * * * an instrument apparatus implement machine contrivance implant in vitro reagent or other similar or related article, including any component, part, or accessory which is * * * intended for use in the diagnosis of disease or other conditions or in the cure mitigation, treatment or prevention of disease in man or other animals * * *, and which does not achieve any of its principle intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes

Latex gloves and other products are subject to this rule, only if they meet the definition of device under section 201(h) of the act Latex gloves that are not used in the cure mitigation treatment or prevention of disease are not devices within the meaning of section 201(h) of the act, and, therefore are not subject to this rule Latex medical gloves that are subject to this regulation include surgeon's gloves, as classified at 21 CFR 878 4460, and patient examination gloves, as classified at 21 CFR 880 6250

FDA also does not agree with the suggestion that OTC medical devices be exempted from the labeling requirements in order to avoid confusion with natural rubber products that are not subject to this rule The purpose of the labeling requirement is to provide essential information for individuals sensitive to natural latex proteins An individual who is sensitive to natural latex proteins is equally likely to react to an OTC device that contains natural rubber, as to a prescription device that contains natural rubber Therefore, it is equally important to provide essential information about OTC devices that contain natural rubber as it is to provide information about prescription devices that contain natural rubber Moreover, the agency does not believe that labeling, as required by this rule, on OTC devices, will cause significant confusion regarding the natural rubber content of consumer products that are not devices

6 Several comments requested clarification on the applicability of the requirements to certain devices Specifically, the comments asked whether the rule would apply to Bandages with natural rubber in the adhesive, natural rubber-free devices packaged in a wrapper using natural rubber in the adhesive, especially where the adhesive would contact human tissue while unwrapping the device, foods or natural rubber-free devices handled or applied with natural rubber latex gloves, covered elastic stretch bands used to attach an accessory or component to a device or, devices intended to contact only subcutaneous tissue

A labeling statement is required for devices that contain natural rubber when the natural rubber contacts humans as described in § 801 437(b) of the final rule Accordingly, devices intended to contact subcutaneous tissue would be required to bear the appropriate statement

Moreover, bandages with natural rubber in the adhesive would require the labeling statement For this product, the natural rubber is intended to be applied directly to the skin If natural rubber-containing adhesives in tapes bindings, and similar items are intended to contact, or are likely to contact, the user or the patient, they are required to be labeled under this regulation Covered elastic bands would not be considered to be in contact with humans provided the covering blocks the migration of natural rubber proteins to the patient and user

FDA does not believe it would be appropriate to require natural rubber labeling statements for natural rubber-free devices or foods that may be handled with latex gloves As described previously in comment 5 of this document, requiring natural rubber labeling for products, such as foods, that are not devices is beyond the scope of this regulation Moreover, FDA does not believe that requiring products that are handled by latex gloves, regardless of whether such products could be within the scope of this regulation as devices, is appropriate if such products do not contain natural rubber Requiring labeling on products that may or may not come into contact with latex gloves would confuse consumers and would be impracticable to implement Furthermore, FDA is not aware of any reports of allergic reactions to rubber-free products that latex gloves have contacted

Under the final rule, natural rubber-containing packaging adhesives that typically are in areas that hold the flaps of packaging together would meet the criteria to subject the product to this rule only if they contact the patient or user However, the agency is not aware of any evidence or reports of reactions to packaging adhesives Given the pervasiveness of the use of adhesives that contain some amount of natural rubber latex, the lack of evidence that these adhesives cause adverse reactions, and the ability to open packaging with adhesives without coming into contact with the adhesives, the agency concludes that the adhesives in device packaging are not intended to contact humans and are not likely to contact humans Therefore, if such adhesives are the sole source of natural rubber in the device packaging or the device itself, a device with such packaging would not be subject to this rule

The agency stresses, however, that it considers device packaging to be an integral part of a device Under section 201(h) of the act, a device includes any components, parts, or accessories As an accessory to a device, the packaging is a device under section 201(h) of the act A device that contains natural rubber in

its packaging beyond that found in the adhesive (e g , a device packaged in a latex sheath) is likely to contact the user or patient and must be labeled as containing natural rubber

In order to avoid confusion and to clarify to the consumer whether it is the device itself or its packaging that contains natural rubber however, the agency believes that a distinct labeling statement is appropriate for devices that have packaging that contains natural rubber that contacts humans Accordingly under § 801 437(f) and (g) of the final regulation, such devices shall have labeling with one of the following statements "Caution The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions ' or "The Packaging of This Product Contains Dry Natural Rubber

The agency notes that if one of these packaging statements is required, it shall appear regardless of whether there is a natural rubber statement relating to the product itself For example, a device that contains dry natural rubber that contacts humans and is also packaged in dry natural rubber that contacts humans shall be labeled with both the statements ' Caution The Packaging of This Product Contains Dry Natural Rubber and 'This Product Contains Dry Natural Rubber "

7 Several comments suggested that the labeling statements be required only on finished medical devices and that device components be exempt

The agency agrees in part The regulation applies to all finished devices and components that are intended to contact or are likely to contact the user or patient The labeling statement does not apply to components shipped directly to a manufacturer or processor for use in the manufacture of a device because these components, during the time before distribution to consumers, would not be intended to contact, or likely to contact the user or patient Under these circumstances, the parts or components are not accessible to health care workers or patients If, however, a device component is sold directly to a consumer including a patient or health care worker, and it is intended to contact or likely to contact a user or patient it is required to be labeled under this regulation, regardless of whether it must be attached, inserted, or used in conjunction with other devices Replacement parts marketed as accessories for medical devices that are intended to contact or likely to contact a user or patient also require the labeling statement

8 One comment suggested that in vitro diagnostic devices be exempt because only dry natural rubber is used, there is usually no patient contact with the natural rubber components and space is very limited for labeling One comment suggested that other devices that do not contact the patient be exempted regardless of whether the natural rubber contacts the tissues of the health care worker

The agency believes that in vitro diagnostic devices should be exempt only to the extent that the natural rubber used in vitro diagnostic devices is not intended to contact or is not likely to contact the user or the patient FDA however, is requiring labeling for such devices if they are intended to contact or are likely to contact health care workers or other users, as well as the patient, because all latex-sensitive persons who use the device need to be informed of the product's natural rubber content

9 One comment requested an exemption for the labeling of natural rubber latex condoms because such condoms clearly contain latex The comment also believed an exemption should apply to latex condoms because space for labeling is limited, a warning regarding allergic reactions may have a chilling effect on the use by individuals who are not sensitive to natural rubber, and the statement may lead to confusion in differentiating between latex and natural skin condoms because natural skin condoms also contain some natural rubber latex and would require the statement as well

The agency disagrees and will require latex condoms to bear a labeling statement that the product contains natural rubber latex that may cause allergic reactions Even though consumers may be aware that the product contains latex, FDA believes that the additional information that natural rubber latex may cause allergic reactions is essential information to individuals who are not aware that natural rubber latex may cause allergic reactions The agency believes that there is sufficient room on condom packaging for the required statement

FDA does not believe that the statement will have a chilling effect on the use of condoms by individuals who are not sensitive to natural latex proteins The statement, however, would clearly provide important information to individuals who are sensitive to natural latex proteins

The agency further disagrees with the suggestion that the labeling statement would be required on natural skin condoms, and thereby confuse consumers with respect to the differences between latex and natural skin condoms Although natural skin condoms do contain a natural rubber elastic band, this band is wrapped within the natural skin sheath, and there is no evidence to indicate that the natural rubber ever contacts the user Therefore, natural skin condoms that have a latex component that is not intended to contact or likely to contact the user do not require the labeling statement Accordingly, the absence of any latex labeling requirement for natural skin condoms obviates the comments concern about confusion that may result from latex labeling statements on both latex and natural skin condoms

10 Although most comments supported the requirements of standard labeling requirements, some comments suggested that the proposed labeling statements were overly prescriptive, and that manufacturers should have wide latitude in the wording of the statement provided it contain a general latex ingredient statement Other comments stated that the labeling statements did not provide sufficient warnings, and suggested that the agency require a caution stating that use of the device may lead to chronic asthma, dermatitis, or even anaphylactic shock and death

The agency does not agree with comments suggesting the labeling should state possible reactions with specificity FDA believes that the statement advising consumers that a product may cause an allergic reaction is specific enough to provide adequate warning

The agency also does not believe that the required labeling statements are overly prescriptive and that manufacturers should be given wide latitude in the wording of labeling statements The agency has determined that requiring standardized statements for devices containing natural rubber is the best approach for providing the essential information in a clear, consistent, and accurate manner

FDA realizes that there may be some circumstances where it may be appropriate to tailor specific information concerning a device. If a manufacturer believes use of statements that vary from those prescribed by this regulation is appropriate, § 801 437(i) of the final regulation provides that the manufacturer may petition the agency for an exemption or variance from these requirements by submitting a citizen petition under 21 CFR 10 30 Unless the agency has specifically granted an exemption or variance, the agency will consider any variation from the required statement to be noncompliant, and the device will be deemed misbranded

11 Several comments suggested that the agency recommend the use of

natural rubber-free devices, or require a labeling statement that nonnatural rubber alternatives are available In contrast some comments supported natural rubber labeling provided that he label be 'ergonomically equitable ' (sic) (i e not giving natural rubber-free devices a perceived advantage)

The agency does not recommend the use of one legally marketed device over another Rather the agency is requiring that labeling for devices that contain natural rubber provide information upon which an individual may make an informed choice regarding the use of the device The benefits of devices that contain natural rubber are well established, and the agency does not intend to discourage their use by persons who are not sensitive to natural rubber Therefore, the agency will not require the labeling statement to recommend the use of rubber-free devices

Furthermore because the agency is not requiring a statement that recommends the use of natural rubber-free devices, the agency does not believe that this rule gives natural rubber-free devices an advantage over devices that contain rubber Accordingly, the agency does not believe that further modifications to the required statements are necessary to address comments that suggested the labeling not give the impression that natural rubber-free products have an advantage over products that contain natural rubber

12 One comment requested clarification on the labeling of combination products consisting of drugs that are packaged in device container vials with dry natural rubber stoppers

This final regulation provides authority to require natural rubber labeling on all devices containing natural rubber, including devices that are contained within combination products As discussed in more detail in this comment, FDA intends to apply the natural rubber labeling requirement to combination products, such as drugs in device containers that are regulated currently under drug authorities

In a final rule that published in the **Federal Register** of November 21, 1991 (56 FR 58754), the agency explained that "the term combination product means a product comprised of two or more different regulated entities, e g , drug, device, or biologic * * *" or two or more different regulated entities that are produced together as a single entity, packaged together, or used together to achieve the intended effect (see 21 CFR 3 2(e)) The fact that a single product contains two or more regulated entities does not in itself change the regulatory status of the individual entities

Because the entities that comprise a combination product meet more than one jurisdictional definition, the agency may apply one or more sets of regulatory provisions to the product The agency, for example has applied both drug and device authorities, and both biological and device authorities, to certain combination products (See Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health (the Drug/Device Agreement (Ref 29)) and Intercenter Agreement Between the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health (the Biologics/Device Agreement (Ref 30)) (hereinafter referred to collectively as the Intercenter Agreements))

Device container vials with dry natural rubber stoppers, when used in combination with a drug product, may be subject to regulation under the statutes and regulations applicable to devices A vial that has a natural rubber stopper meets the definition of a device under section 201(h) of the act, in that such vial is "an instrument, apparatus implement machine, contrivance, implant, in vitro reagent, or some other similar or related article, including any component part, or accessory * * *" that is intended to cure, mitigate treat, or prevent disease, which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes The agency regulates these empty vials, as well as other empty drug or biologic containers (such as stoppered vials for use in blood collection, intravenous containers, and blood bags), as devices

When the drug is contained in a vial, however, the result is a combination product The combination status of devices that serve as containers for drugs is specifically recognized in the Drug/Device Agreement (See Ref 29, p 14) To date, these combination products have been regulated only under the drug authorities (*Id*)

The agency intends to require that all combination products that contain natural rubber device components be labeled in accordance with this regulation Although the agency could require all combination natural rubber products to comply with the regulation on its effective date, this regulation will be applied as follows Natural rubber combination products that are currently listed in the Intercenter Agreements as being regulated under device labeling provisions will be required to comply with this rule on its effective date, natural rubber combination products that are listed in the Intercenter Agreements as being regulated under drug or biologic labeling provisions, however, will be subject to this regulation at the time of the effective date of this regulation, or at the time the Intercenter Agreements are amended to provide that these types of combination products are subject to this labeling regulation, whichever is later FDA will provide notice in the **Federal Register** of the amendments to the Intercenter Agreements to apply this natural rubber labeling provision to all combination products that contain natural rubber device components

At this time, the agency anticipates that the Drug/Device Intercenter Agreement will be amended to reflect that prefilled drug vial containers, transdermal patches, infusion pumps, and prefilled syringes that presently are regulated under drug authorities are also subject to this regulation The agency believes, however, that this requirement will not affect many drug vial containers, because most drug stoppers are not being manufactured from dry natural rubber

13 A few comments requested clarification on the applicability of the requirements to devices already in the marketplace or intended solely for export

This rule is not intended to require manufacturers to recall any devices already in interstate commerce. Therefore, this rule does not apply to devices initially introduced or initially delivered for introduction into interstate commerce before the effective date of this regulation

Devices intended solely for export will not be deemed misbranded for failure to comply with this regulation provided that the exporter meets the criteria of sections 801(e) and 802 of the act (21 U S C 381(e) and 382) Nevertheless, FDA encourages the application of a natural rubber content statement to all exported devices containing natural rubber that may contact humans

14 A few comments suggested that devices containing less than a minimum quantity of natural rubber, the amount to be determined by the agency, be exempt from the labeling requirement One comment suggested that devices be labeled with the extractable natural latex protein content

The agency agrees in principle, however, insufficient information currently exists regarding the minimum

amount of extractable natural latex protein that would not elicit an allergic reaction for this option to be practicable Evidence indicates that some persons re reactive to extremely low levels of proteins (Ref 31) The agency is unable to determine what minimum amount of natural latex proteins fails to elicit a reaction in some individuals and, therefore cannot exempt devices containing less than that minimum

15 Several comments requested clarification on the level of packaging that would require a labeling statement Some comments requested additional flexibility in the placement of the statement so that the statement may be put on the device labeling other than the label especially where the device label may be too small to carry such a statement Another comment recommended that the statement be required not only on the label and in other labeling, but on the device itself if the device is dispensed in bulk, as in the case with natural rubber latex examination gloves Other comments suggested that bulk devices either remain in the original package in order to preserve the label, or that the agency require the user facility to educate and monitor the use of bulk devices containing natural rubber Still another comment suggested that where bulk devices are removed to a separate dispensing container the dispensing container also be required to be labeled with a natural rubber content statement

FDA believes that the required labeling statements may be fitted on small labels Because of the importance of the information contained in the labeling statements for individuals sensitive to natural latex proteins, the agency will require the appropriate statements concerning the natural rubber content of the products to be prominently and legibly displayed on all device labels and other labeling, and to appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper

This means, for example, that the labeling statement for adhesive bandages that are individually wrapped and sold in a box would appear on each individually wrapped bandage, on the box, and on any individual pieces of labeling, such as an instructions for use sheet included in the box Devices packaged and sold in bulk dispensing containers would be required to display the appropriate statement on the dispensing container, as it is the immediate device container or package

If the packaging of a device contains natural rubber the final regulation requires that a separate statement that specifically cautions the user that the natural rubber is contained in the packaging itself Statements relating to the natural rubber content of the packaging do not have to appear on the same levels of labeling as the cautionary statements relating to natural rubber content in the actual product The statements cautioning the user that the packaging contains natural rubber shall appear, instead, only on the packaging that contains the natural rubber, and the outside package, container, or wrapper Placement of cautionary statements in these locations should warn consumers adequately of the possible risks of allergic reactions to the packaging, while avoiding the potential for confusion that the actual products contain natural rubber

FDA believes that requiring devices to remain in their original package at the user site, requiring labeling statements on dispensers that are sold separately from the natural rubber containing devices, and requiring user facilities to provide education concerning latex products and to monitor bulk product use, is impracticable and beyond the scope of the regulation Furthermore, because of the potential manufacturing difficulties the agency will not require devices to be embossed imprinted, or otherwise labeled on the individual, unwrapped device The agency believes that the labeling requirements in this regulation will provide adequate protection to the users and patients

16 The vast majority of comments supported the removal of the "hypoallergenic' claim from the labeling of medical devices that contain natural rubber Those comments that expressed unease about the removal of the claim stated that the term does convey meaningful information to the user These comments suggested that an alternative term be applied, or that the regulation allow device labeling to state that the device presents a reduced potential for sensitizing users to natural rubber or that the device contains less than a specified limit of natural latex proteins or processing chemicals as established by the agency One comment stated that, until the agency proves that the tests currently employed are insufficient to support the "hypoallergenic" claim, the claim should be allowed

The agency agrees that the term "hypoallergenic" provides important information to the consumer who is sensitive to processing chemicals but believes that the term "hypoallergenic" on products containing natural rubber will mislead consumers to conclude erroneously that the product may not cause latex protein allergic reactions

In the past, manufacturers have labeled their products "hypoallergenic' on the basis of results of the modified (human) Draize test While this test may be appropriate for detecting sensitivity to residual levels of processing chemicals, the test cannot detect the presence of natural latex proteins Furthermore, current manufacturing processes cannot reduce the levels of natural latex proteins below that to which some individuals may react

The agency disagrees that the 'hypoallergenic" label should be allowed to remain on devices that contain natural rubber until the agency proves that the tests currently employed are insufficient to support the "hypoallergenic' claim, or that claims should be allowed regarding reduced levels of latex proteins The agency has received reports of allergic reactions to natural rubber gloves labeled as hypoallergenic Given that the modified (human) Draize Test is not designed to detect levels of natural latex proteins that would not induce allergic responses, and that the agency is not aware of any current manufacturing processes that are designed to remove latex proteins below a level that may cause adverse reactions, the agency believes that it has sufficient evidence that the tests currently employed do not support the claim "hypoallergenic" with respect to the potential for allergic reactions to natural latex proteins

The agency does agree that alternative statements should be applied to convey information about devices with reduced residual chemical levels to consumers who are sensitive to chemicals For this reason, the agency is developing guidance for manufacturers who want to make claims relating to latex devices that have reduced manufacturing chemical residues FDA will announce the availability of this draft guidance document entitled "Testing for Skin Sensitization to Chemicals in Latex Products" in a future issue of the **Federal Register**

17 A few comments stated that the reference to the draft guidance document entitled "Testing for Skin Sensitization to Chemicals in Latex Products" in the preamble to the June 24, 1996 proposed rule, upon which this final rule is based, was inappropriate because the document is still in draft form, while another comment suggested the agency reference the draft guidance document in the regulation itself

The agency does not believe it is appropriate to incorporate a draft guidance document into a regulation The agency, however, does believe that

it is appropriate to use the preambles of a proposed and final rule relating to latex devices to inform the public that the agency is in the process of developing a guidance document relating to claims about the sensitizing potential of manufacturing chemical residues in latex devices

18 The vast majority of comments supported the use of a symbol to indicate the presence of natural rubber in a device These comments stated that the symbol would promote consumer recognition and could be used on devices that have labels that are too small to fit the full text of the statement One comment suggested that the symbol be stamped on the actual devices, especially those sold in bulk packages Some comments stated that the symbol should supplement, not replace the text of the statement Those comments not supporting the use of a natural rubber symbol cautioned that a symbol should not be used until it is universally accepted Another comment suggested that the agency establish the symbol and require its use

The agency agrees that a symbol would be useful The agency stresses, however that any symbol is intended to supplement not replace the required written labeling statements and its use would be voluntary The agency appreciates the comments and the suggested symbol designs that were submitted, but does not believe that there is sufficient acceptance of a symbol to require the use of a symbol at this time

19 Several comments stated that the health benefits of the labeling statement are potentially so great that the effective date of the requirement should be less than 180 days from the date of publication of this final rule Other comments complained that a 180-day implementation period is not sufficient to change the labeling on the numerous devices affected by this rule These comments requested at least a 12-month implementation period One of these comments further requested that implementation be a two-stage process, and that devices containing dry natural rubber not be required to carry the labeling statement until 24 months after publication of this final rule Another comment requested a two-stage implementation process so that devices that only indirectly contact humans would not be required to carry the labeling statement until 36 months after publication, or that such devices not be required to carry any labeling statement

The agency agrees that the public health concerns relating to allergic responses to natural rubber are great The agency also acknowledges, however, that at the time of the publication of this regulation, manufacturers have labeling in stock that does not have the required statements In order to minimize the burden to manufacturers of discarding labeling that has already been printed, and to allow sufficient time to reformat labeling the agency is providing that the effective date of this final rule is 1 year after the date of publication This effective date will allow most manufacturers sufficient time, before the effective date of this rule, to exhaust their existing supply of labeling stock If a manufacturer uses the existing labeling stock before the effective date of this rule however FDA encourages manufacturers to add the required labeling statement at that time

The agency does not believe that a two-stage implementation process is necessary, or that a period of longer than 1 year is necessary because 1 year should be adequate time to phase in new labeling, and reformat the labeling Furthermore the agency believes that a longer delay in the implementation of this rule would not be in the interest of the public health The comment suggesting that devices that only indirectly contact humans not carry any natural rubber labeling statement is addressed in comment 4 of this document

20 One comment suggested that manufacturers, distributors, and user facilities all be responsible for following the labeling requirements

The agency agrees with the underlying concern that the labeling statement remain on devices It is only necessary, however, to require manufacturers to properly label their products to ensure that consumers receive appropriate information concerning natural rubber products Distributors and user facilities may not alter the device labeling Any such alteration may be grounds for a charge of misbranding a device under sections 201(n) and 502(a), (c), and (f) of the act (21 U S C 352(a), (c), and (f))

21 A few comments complained that the rule could be misinterpreted to require labeling on all devices containing any natural rubber whatsoever Others stated that the requirement would have a major impact on multinational companies, costing at least $15,000 per device for labeling Another comment stated that the agency underestimated the impact of the rule, as each manufacturer will need to draft, review, and relabel primary and secondary packages of hundreds, if not thousands of devices

The agency has clarified the scope of this regulation in order to minimize the possibility of misinterpretation Under final § 801 437(b), an appropriate labeling statement is required on medical devices that contain natural rubber latex or dry natural rubber that contacts humans The agency does not believe that this rule would require relabeling for hundreds or thousands of devices In fact, the agency has only identified approximately 70 generic types of medical devices including combination products that are subject to this rule

Furthermore, FDA does not agree that this rule will have a major impact on multinational companies because it would cost at least $15,000 per device for labeling FDA estimates that the cost to revise the labeling would be between $1,000 and $2,000 for each type of device that is relabeled Moreover, the cost of implementing this regulation is further minimized because the 1-year effective date of this regulation should allow most manufacturers to exhaust their current labeling stock prior to using the labeling that is required under this regulation

IV Paperwork Reduction Act of 1995

The warning statements required by this regulation are "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public * * *" (5 CFR 1320 3(c)(2)) Accordingly, FDA concludes that the labeling requirements in this final rule are not subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U S C 3501–3520)

V Environmental Impact

The agency has determined under 21 CFR 25 24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment Therefore, neither an environmental assessment nor an environmental impact statement is required

VI Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U S C 601–612), as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub L 104–4) Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity) The

agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order

If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities This rule primarily requires a labeling change which would not have a significant economic impact on small entities Although this rule will require a labeling change on a substantial number of medical devices manufacturers will be allowed up to 1 year after the effective date of this regulation to exhaust their existing supply of labeling, therefore most manufacturers would exhaust their existing supply of labels Moreover, the cost of reformatting the labeling, which is $1 000 to $2,000 for each different kind of device, is not significant Accordingly, under the Regulatory Flexibility Act (5 U S C 605(b)), the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities Therefore under the Regulatory Flexibility Act no further analysis is equired

VII References

The following references have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr rm 1-23 Rockville, MD 20857, and may be seen by interested persons between 9 a m and 4 p m , Monday through Friday

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List of Subjects in 21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 801 is amended as follows

PART 801—LABELING

1 The authority citation for 21 CFR part 801 continues to read as follows

Authority: Secs 201, 301, 501, 502, 507, 519, 520, 701 704 of the Federal Food, Drug, and Cosmetic Act (21 U S C 321, 331, 351 352, 357, 360i 360j, 371, 374)

2 Section 801 437 is added to subpart H to read as follows

§ 801.437 User labeling for devices that contain natural rubber.

(a) Data in the Medical Device Reporting System and the scientific literature indicate that some individuals are at risk of severe anaphylactic reactions to natural latex proteins This labeling regulation is intended to minimize the risk to individuals sensitive to natural latex proteins and protect the public health.

(b) This section applies to all devices composed of or containing, or having packaging or components that are composed of, or contain, natural rubber that contacts humans The term "natural

rubber includes natural rubber latex dry natural rubber and synthetic latex or synthetic rubber that contains natural rubber in its formulation

(1) The term "natural rubber latex" means rubber that is produced by the natural rubber latex process that involves the use of natural latex in a concentrated colloidal suspension Products are formed from natural rubber latex by dipping, extruding, or coating

(2) The term 'dry natural rubber" means rubber that is produced by the dry natural rubber process that involves the use of coagulated natural latex in the form of dried or milled sheets Products are formed from dry natural rubber by compression molding, extrusion or by converting the sheets into a solution for dipping

(3) The term ' contacts humans" means that the natural rubber contained in a device is intended to contact or is likely to contact the user or patient This includes contact when the device that contains natural rubber is connected to the patient by a liquid path or an enclosed gas path or the device containing the natural rubber is fully or partially coated with a powder, and such powder may carry natural rubber proteins that may contaminate the environment of the user or patient

(c) Devices containing natural rubber shall be labeled as set forth in paragraphs (d) through (h) of this ection Each required labeling statement shall be prominently and legibly displayed in conformance with section 502(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U S C 352(c))

(d) Devices containing natural rubber latex that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling

"Caution This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions '

This statement shall appear on all device labels and other labeling, and shall appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container or wrapper

(e) Devices containing dry natural rubber that contacts humans, as described in paragraph (b) of this section that are not already subject to paragraph (d) of this section, shall bear the following statement in bold print on the device labeling

"This Product Contains Dry Natural Rubber '

This statement shall appear on all device labels, and other labeling, and shall appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package container or wrapper

(f) Devices that have packaging containing natural rubber latex that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling

Caution The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions '

This statement shall appear on the packaging that contains the natural rubber, and the outside package, container, or wrapper

(g) Devices that have packaging containing dry natural rubber that contacts humans, as described in paragraph (b) of this section, shall bear the following statement in bold print on the device labeling

The Packaging of This Product Contains Dry Natural Rubber "

This statement shall appear on the packaging that contains the natural rubber, and the outside package, container, or wrapper

(h) Devices that contain natural rubber that contacts humans, as described in paragraph (b) of this section, shall not contain the term "hypoallergenic" on their labeling

(i) Any affected person may request an exemption or variance from the requirements of this section by submitting a citizen petition in accordance with § 10 30 of this chapter

(j) Any device subject to this section that is not labeled in accordance with paragraphs (d) through (h) of this section and that is initially introduced or initially delivered for introduction into interstate commerce after the effective date of this regulation is misbranded under sections 201(n) and 502(a), (c), and (f) of the act (21 U S C 321(n) and 352(a), (c), and (f))

Dated September 22 1997

William K Hubbard,

Associate Commissioner for Policy Coordination

[FR Doc 97-25728 Filed 9-29-97, 8 45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice 2610]

Bureau of Consular Affairs; Visas: Passports and Visas Not Required for Certain Nonimmigrants

AGENCY: Bureau of Consular Affairs DOS

ACTION: Interim rule with request for comments

SUMMARY. Section 217 of the Immigration and Nationality Act (INA), as amended, extends the Visa Waiver Pilot Program (VWPP) to nationals of all countries that qualify under the provisions of the Pilot Program and which are designated by the Secretary of State and the Attorney General as countries whose nationals benefit from the waiver of the nonimmigrant B-1/B-2 visa requirement This interim rule eliminates probationary entry status in the pilot program, designates Ireland (the only country formerly designated as a participating country with probationary status) as a permanent participating country and extends the VWPP to Slovenia

DATES: This interim rule is effective September 30, 1997 Written comments are invited and must be received on or before October 30, 1997

ADDRESSES: Written comments may be submitted, in duplicate, to the Chief, Legislation and Regulations Division, Visa Services, Room L-603C, Department of State, Washington, D C 20520-0106

FOR FURTHER INFORMATION CONTACT: H Edward Odom, Chief, Legislation and Regulations Division, Visa Office, Department of State, Washington, D C 20522-0113 (202) 663-1203

SUPPLEMENTARY INFORMATION: This interim rule amends Part 41, Title 22 of the Code of Federal Regulations concerning visas for nonimmigrants pursuant to section 217 of the Immigration and Nationality Act, 8 U S C 1187, as amended by Pub L 103-415, (108 Stat 4299, October 25,1994), Pub L 103-416, (108 Stat 4305, October 25, 1994), and Pub L 104-208, (110 Stat 3009-702, September 30, 1996)

Pub L 99-603

Section 313 of the Immigration Reform and Control Act of 1986 (IRCA), Pub L 99-603, amended the INA by adding a new section 217 (8 U S C 1187) Section 217 provides for a nonimmigrant visa waiver pilot program (VWPP) which waives the nonimmigrant visa requirement for the admission of certain aliens into the United States for a period not to exceed ninety days This original provision authorized the participation of eight countries in the VWPP to be designated by the Secretary of State and the Attorney General, acting jointly from among countries meeting specific criteria These original qualifying countries included France, the Federal

OSHA Tech. Info. Bulletin

Technical Information Bulletin

Technical Information Bulletin - Potential for Allergy to Natural Rubber Latex Gloves and other Natural Rubber Products.

- **Record Type:** Technical Information Bulletin
- **Subject:** Potential for Allergy to Natural Rubber Latex Gloves and other Natural Rubber Products.
- **Information Date:** 19990412

April 12, 1999

MEMORANDUM FOR REGIONAL ADMINISTRATORS

THROUGH R DAVIS LAYNE
Deputy Assistant Secretary

FROM: STEVEN F. WITT
Director
Directorate of Technical Support

SUBJECT Technical Information Bulletin[1]:
Potential for Allergy to Natural
Rubber Latex Gloves and other Natural
Rubber Products

This technical information bulletin is intended to alert field personnel to the potential for allergic reactions in some individuals using natural rubber latex (NRL) products, particularly gloves, in the workplace setting. Natural rubber is utilized in a variety of products including gloves, airways, airway masks, medication vial tops, anesthesia bags, various catheters, supplies for intravenous use, dental dams, balloons, and other products.[1,2,3] NRL glove use in the health care setting has risen dramatically since about 1987, due to the increased threat of contracting HIV, hepatitis B, and other infectious agents in the course of delivering health care to patients and the need for barrier protection.[1,4] Thus, the frequency of exposure to NRL among health care and other workers has increased.

NRL products are also used to provide barrier protection from some chemicals and other agents in health care and other environments. (NOTE: While NRL gloves are useful for certain purposes, they are not universally suitable. The properties of a glove material for a specific use must be determined in advance of use. Gloves appropriate for protection from the particular chemical or agent must be used.) NRL gloves are also used to prevent contamination of products in some workplaces (e.g., electronics and drug manufacturing). Natural rubber articles are manufactured in some workplaces (e.g., manufacturers of medical gloves, industrial gloves, balloons, rubber bands, boots and shoes, and many other products).

With more widespread use of NRL gloves, there has been an increase in reported NRL allergies, among patients as well as among workers, notably health care workers. Rarely, these allergies can be fatal. In addition to reports from the dermatology, allergy, and pulmonary literature of severe skin and respiratory symptoms, life threatening reactions to NRL products have been

noted in pediatric patients with spina bifida who had undergone numerous surgical procedures, resulting in repeated NRL exposure.[5,6,7] In addition, the US Food and Drug Administration (FDA) received reports of numerous severe allergic reactions, including several deaths, associated with exposure to NRL enema cuffs in providing care to sensitized patients.[8]

NRL is manufactured from a variety of plants, but mainly the rubber tree, ***Hevea brasiliensis***. The milky fluid from the tree contains variable amounts of proteins which may be absorbed through the skin or inhaled and cause allergic reaction in susceptible workers NRL contains many proteins. A number of these proteins, such as hevamine, hevein, and rubber elongation factor (REF), may initiate allergic reaction to NRL. Studies have indicated that corn starch powder, added to gloves to facilitate donning and removal, can serve as a carrier for the allergenic proteins from the NRL.[2,3,9]

In addition, gloves, including those made from NRL as well as some other materials, may contain chemical accelerators such as thiuram, carbamates, and benzothiazoles to which a worker may also develop sensitization, resulting in allergic contact dermatitis. Antioxidants, biocides, soaps, and other chemicals used in the processing of NRL products may contribute to sensitization as well.

In 1987 the Centers for Disease Control and Prevention (CDC) recommended universal precautions, the concept that blood and certain body fluids from all individuals should be approached as if potentially infectious. The use of barrier protection was subsequently required by OSHA's bloodborne pathogens standard. The increased use of latex gloves in a variety of settings greatly increased the exposure of health care workers to NRL.[1,4]

The two major routes of exposure include dermal exposure and inhalational exposure. NRL protein absorption has been reported to be enhanced when perspiration collects under latex clothing articles.[10] Exposure may also occur by the respiratory route, particularly when glove powder acts as a carrier for NRL protein which becomes airborne when the gloves are donned or removed.[2,3,9] Some investigations have indicated that powder free gloves with reduced protein content reduce risk of development of NRL allergy.[11] Some questions regarding powder free glove shelf life and ease of use have arisen and are being addressed. Importantly, only non-NRL gloves must be used by those workers who are allergic to NRL.

The majority of health care workers are able to use NRL products to care for most patients. Variations exist in the reported prevalence of NRL allergy. This variation is probably due to different levels of exposure and methods of estimating latex sensitization or allergy. Nevertheless, prevalence studies indicate that from around 6% to 17% of the exposed health care workforce is allergic to NRL.[5,12,13,14,15] In a survey of active duty dental officers in the U.S. Army, the prevalence of allergic symptoms correlated with NRL use was reported to be 13.7%.[16] An investigation of dental workers using NRL skin prick testing at two consecutive American Dental Association meetings revealed allergic responses in 9.1-9.7% of dental hygienists and assistants, although dentists showed a lower rate of 5.1-6.7%.[17] The general population exhibits a lower rate of NRL sensitization (approximately 1 to 6%).[18,19] These prevalence statistics are based on seroprevalence as well as skin test positivity and/or allergic manifestations and do not refer to the more serious anaphylactic response, which is rare but potentially life threatening in some individuals.

In addition to dentists, health care workers reported to have especially high risks include operating room personnel consistently exposed to NRL (i.e., operating room nurses, physicians, and technicians).[3,18]18 NRL allergy has also been reported in greenhouse workers,[20]hairdressers,[21] doll manufacturing workers,[22] and workers in a glove manufacturing plant,[23] and may pose a risk to others as well.[24]

Use of natural rubber products may result in several varieties of reactions (see table). These reactions include irritant and several types of allergic reactions. They can vary from localized redness and rash to nasal, sinus, and eye symptoms to asthmatic manifestations including cough, wheeze, shortness of breath, and chest tightness; and rarely, systemic reactions with swelling of the face, lips, and airways that may progress rapidly to shock and, potentially, death.

When gloves are associated with skin lesions, the most common reaction is irritant contact dermatitis. Irritant contact dermatitis may be due to direct irritation from gloves or glove powder, but may also be due to other causes, such as irritation from soaps or detergents, other chemicals, or incomplete hand drying. Irritant contact dermatitis presents as dried, cracked, split skin. Although irritant contact dermatitis is not in itself an allergic reaction, the breaking of the intact skin barrier due to these lesions may afford a pathway for latex proteins to gain access, and thus promote development of allergy.[25]

The second type of reaction that may be associated with glove use is allergic contact dermatitis (also known as type IV delayed hypersensitivity or allergic contact sensitivity). When glove use has been associated with this reaction, it appears to be due to the chemicals used in processing NRL or other glove materials. The allergic contact dermatitis has an appearance similar to the typical poison ivy reaction, with blistering, itching, crusting, oozing lesions. Also, like poison ivy, this dermatitis may appear a day or two after the use of gloves or exposure to other sources of chemical sensitizers.

The third and potentially most serious type of reaction sometimes associated with glove use is a true IgE/histamine-mediated allergy (also called immediate or type I hypersensitivity) to glove protein [in the case of NRL allergy, to NRL protein(s)]. This type of reaction can involve local or systemic symptoms. Localized symptoms include contact urticaria (hives) which appear in the area where contact occurred (in the case of gloves, the hands), but which can spread beyond that area and become generalized. More generalized reactions include allergic rhinoconjunctivitis and asthma. The presence of allergic manifestations to NRL indicates an increased risk for anaphylaxis, a rare but serious reaction experienced by some individuals who have developed an allergy to certain proteins (e g., insect stings, natural rubber, penicillin). This type I reaction can occur within seconds to minutes of exposure to the allergen (in the case of NRL, to natural rubber proteins) either by touching a product with the allergen (e.g., gloves) or by inhaling the allergen (e.g., powder to which natural rubber proteins from gloves have adsorbed). When such a reaction occurs, it can progress rapidly from swelling of the lips and airways to shortness of breath, and may progress to shock and death, sometimes within minutes. While any of these signs and symptoms may be the first indication of allergy, in many workers with continued exposure to the allergen (in the case of NRL allergy, to natural rubber proteins), there is progression from skin

Types of Reactions

Type Reaction	**Symptoms/Signs**	**Cause**	**Prevention / Management**
Irritant Contact Dermatitis	scaling, drying, cracking of skin	direct skin irritation by gloves, powder, soaps/detergents, incomplete hand drying	Obtain medical diagnosis, avoid irritant product, consider use of cotton glove liners , consider alternative gloves/products
Allergic Contact Dermatitis (Type IV delayed	blistering, itching, crusting (similar to poison ivy reaction)	accelerators (e.g., thiurams, carbamates	Obtain medical diagnosis, identify chemical

delayed hypersensitivity **or** allergic contact sensitivity)	poison ivy reaction)	carbamates, benzothiazoles) processing chemicals (e.g., biocides, antioxidants) Consider penetration of glove barrier by chemicals	chemical. Consider use of glove liners such as cotton Use alternative glove material without chemical Assure glove material is suitable for intended use (proper barrier)
NRL Allergy - IgE/histamine mediated (Type I immediate hypersensitivity) --- A) Localized contact urticaria ***which may be associated with or progress to:*** B) Generalized Reaction	--- Hives in area of contact with NRL --- Include: generalized urticaria, rhinitis, wheezing, swelling of mouth, shortness of breath. Can progress to anaphylactic shock	NRL proteins: direct contact with or breathing NRL proteins, including glove powder containing proteins, from powdered gloves or the environment	Obtain medical diagnosis, allergy consultation, substitute non-NRL gloves for affected worker and other non-NRL products Eliminate exposure to glove powder - use of reduced protein, powder free gloves for coworkers Clean NRL-containing powder from environment Consider NRL safe environment

(contact urticaria) to respiratory symptoms over a period of months to years. Some studies indicate that individuals with latex allergy are more likely than latex non-allergic persons to be atopic (have an increased immune response to some common allergens, with symptoms such as asthma or eczema. [26] Once NRL allergy occurs, allergic individuals continue to experience symptoms, which have included life-threatening reactions, not only on exposure to NRL in the workplace but also upon receiving or accompanying a family member receiving health care services at inpatient as well as office-based settings. In addition, such reactions have occurred on exposure to consumer goods such as balloons, condoms, and other products. Moreover, some affected individuals continue to experience asthmatic symptoms even without contact with NRL. Therefore, development of allergy to NRL in an individual has lifestyle implications beyond the workplace.

Recommended Strategies - Risk Reduction

It is of primary importance that barrier protection be used when hands would otherwise contact infectious materials or hazardous chemicals. OSHA's bloodborne pathogens standard requires that gloves be worn when it is reasonably anticipated that hand contact may occur with blood, other potentially infectious materials, mucous membranes, non-intact skin, or contaminated items or surfaces, as well as when performing most vascular access procedures [29 CFR 1910.1030, paragraph (d)(3)(ix)]. NRL is a glove material that has been used in the health care environment for barrier protection for a number of years. In response to reported NRL allergy in

some patients and health care workers, measures have been recommended to reduce the risk of NRL allergy in workers.

Primary prevention involves reducing potential development of allergy by reducing unnecessary exposure to NRL proteins for all workers. Food service workers or gardeners, for example, do not need to use NRL gloves for food handling or gardening purposes. Gloves made of NRL as well as synthetic materials have been cleared for marketing as medical gloves by the FDA and can be used effectively for barrier protection against bloodborne pathogens. General administrative procedures[2A] that an institution can follow to reduce worker exposure to NRL proteins include:

(1) If selecting NRL gloves for worker use, designating NRL as a choice only in those situations requiring protection from infectious agents;

(2) When selecting NRL gloves, choosing those that have lower protein content. [18] Selecting powder free gloves offers the additional benefit of reducing systemic allergic responses; and

(3) Providing alternative suitable non-NRL gloves as choices for worker use (and as required by OSHA's bloodborne pathogens standard [29 CFR 1910.1030, paragraph (d)(3)(iii)] for workers who are allergic to NRL gloves).

Providing alternative suitable non-NRL gloves as choices for worker use (and as required by OSHA's bloodborne pathogens standard [29 CFR 1910.1030, paragraph (d)(3)(iii)] for workers who are allergic to NRL gloves).

Use of powder free gloves has been shown to reduce the dissemination of NRL proteins into the environment and decrease the likelihood of reactions by both the inhalation and dermal routes [2,27] Appropriate work practices when wearing hand protective equipment, including NRL gloves, include avoidance of contact with other body areas such as the eyes or face. Handwashing after glove removal is required by OSHA's Bloodborne Pathogens Standard [paragraph (d)(2)(v)] and helps to minimize powder and/or NRL remaining in contact with the skin. Thorough clean-up of any residual powder in the workplace with appropriate vacuum filters will decrease employees' exposure as well.

Since the reason for wearing gloves is to provide barrier protection from hazardous substances, substitute materials must maintain an adequate barrier protection and be appropriate for the hazard. At a minimum, gloves made from NRL or other materials and used for a medical purpose should be labeled as medical gloves. Such gloves must meet the FDA criteria for marketing, manufacturing, and testing of medical gloves. The Health Industry Manufacturers Association (HIMA), in conjunction with the FDA, has proposed general guidelines for use of medical gloves with some recommendations for those individuals who are allergic to natural rubber.[28]

One institution has reported that a coordinated effort to identify NRL sensitive individuals and reduce the use of "high allergenic" natural rubber latex gloves substantially reduced aeroallergen levels and costs.[4] Other investigators have reported that some NRL allergic workers have been able to work wearing nonlatex gloves when their coworkers wore powder free latex gloves. [29]

Effective September 30, 1998, the FDA requires labeling statements for medical devices which contain natural rubber and prohibits the use of the word "hypoallergenic" to describe such products.[8] NRL gloves with a reduced level of chemical accelerators must be labeled to eliminate confusion associated with the "hypoallergenic" claim and to provide more specific information to the user. Some NRL gloves and other devices produced before the effective date of the FDA regulation may not carry the NRL labeling or may be labeled "hypoallergenic". Such products

may still be in use in some facilities. It should be noted that such products should not be presumed to be NRL free. The hypoallergenic claim referred to the chemical additives, and such gloves may be powder free; however, they contain the NRL proteins to which NRL allergic workers react.[30] The FDA is currently exploring options for reducing exposure to NRL proteins and powder. It is important to note that these FDA regulations do not apply to non-medical devices, including utility gloves.

Recommended Worker Evaluation and Management

The administrative procedures outlined above may not be sufficient to protect all individuals who have already developed NRL allergy. The American College of Allergy, Asthma, and Immunology has suggested that "safe zones" (areas in which non-NRL products are used and NRL proteins have been thoroughly removed from the environment) may be needed to protect those workers who are already sensitized to NRL.[5] Health care facilities should develop policies and procedures for reducing the risk of NRL allergies in the workplace. Prudent risk reduction strategy involves an initial survey and assessment, with a coordinated effort to identify and catalogue all NRL products used in the workplace. An ongoing program, involving close coordination with resource and materials management staff, should be established to monitor the NRL content of incoming products so that management staff can be prepared to choose appropriate products for offering non-NRL alternatives to control NRL exposure as well as for creating NRL safe zones.[2] Mechanisms for reporting and managing cases should be in place.

It is not possible, at present, to determine which workers will become allergic to NRL proteins, the extent of an individual worker's reaction, or the length of time required for such allergic reactions to develop.[3] It is also not possible, at present, to predict who will progress from local contact urticaria to the more dangerous allergic reactions, nor when this may occur. [2,3]

Laboratory and clinical evidence indicates that an association exists between allergy to natural rubber proteins and allergy to certain foods and plants (e.g., avocado, banana, kiwi, chestnut) [31] and some aeroallergens (e.g., pollens, grasses).[32] A history of multiple surgeries has also been reported to be a risk factor for NRL allergy [2, 5] In some institutions, periodic screening questionnaires for symptoms of NRL allergy in workers with current or past history of significant NRL exposure (e.g., surgical personnel) have been useful for ascertaining reaction rates and managing those individuals experiencing reactions. [3,5,30] A medical evaluation of hand dermatitis, by a physician experienced in dermatologic diagnoses, is essential for taking preventive steps and assuring effective therapeutic measures. Evaluation of signs/symptoms associated with latex allergy should be accomplished under the direction of a physician with expertise in NRL allergy, with additional medical testing and treatment made available if indicated.

Provision of latex-free procedure trays and crash carts for treatment of natural rubber allergic individuals has been recommended.[5] Although the fundamentals of emergency response

(i.e., assuring airway, breathing, and circulation) remain of primary importance should a worker develop symptoms (including those caused by NRL allergy) requiring resuscitation, these situations should be anticipated in the workplace and provision of immediate access to non-natural rubber containing equipment considered.

Information Availability

Investigation continues into various aspects of NRL allergy; our understanding of some issues continues to evolve. Meanwhile, workers and workplaces need to be aware of the present state of knowledge regarding NRL allergy and methods of protection. Workers should be advised of symptoms of NRL allergy as well as primary and secondary preventive measures for decreasing

the risk of NRL allergy development and NRL allergic reactions in workers who are allergic.

The National Institute for Occupational Safety and Health (NIOSH) published a 1997 Alert titled Preventing Allergic Reactions to Natural Rubber Latex in the Workplace (NIOSH publication number 97-135). NIOSH can be reached by calling 1-800-35-NIOSH (800-356-4674).

OSHA field staff and consultation personnel should be aware of the potential for NRL allergy in workers exposed to NRL products.

Please distribute this bulletin to all Area Offices, State Plan States, and Consultation Projects. Copies of this TIB may be used for outreach purposes.

This technical information bulletin (TIB) is not a new standard or regulation. This TIB is advisory in nature and informational in content. The failure to implement a specific recommendation in this TIB is not in itself a violation of the General Duty Clause of the OSH Act. The General Duty Clause [Section (5)(a)(1)] requires each employer to furnish to each employee employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees.

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1A. The Directorate of Technical Support issues technical information bulletins (TIBs) to provide OSHA field staff with information regarding safety and health issues. TIBs are initiated based on information provided by the field staff, scientific investigations, technical publications, and concerns expressed by safety and health professionals, employers, and the public. This information has been compiled based on a thorough evaluation of available facts, and in coordination with appropriate parties. (Back to Text)

2A. The American Academy of Allergy, Asthma, and Immunology and American College of Allergy, Asthma, and Immunology issued a joint statement July 21, 1997 which advises that latex glove purchase and use should consist of only low-allergen, powder-free latex gloves. The National Institute for Occupational Safety and Health (NIOSH) also recommends that if latex gloves are chosen, provide and use reduced protein, powder-free gloves.[18] A 1998 Guideline for infection control in health care personnel, consisting of consensus recommendations of the Hospital Infection Control Practices Advisory Committee (HICPAC) to the CDC, included several recommendations regarding latex hypersensitivity, but did not include advice about use of powder-free gloves throughout an institution and made no recommendation for institution-wide substitution of non-latex products in health care facilities to prevent sensitization to latex (Am J Infection Control 1998;26:339). (Back to Text)

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15 U.S.C 1261 (K)

TITLE 15--COMMERCE AND TRADE

CHAPTER 30--HAZARDOUS SUBSTANCES

Sec 1261 Definitions

For the purposes of this chapter--

(a) The term ``territory'' means any territory or possession of the United States, including the District of Columbia and the Commonwealth of Puerto Rico but excluding the Canal Zone.

(b) The term ``interstate commerce'' means (1) commerce between any State or territory and any place outside thereof, and (2) commerce within the District of Columbia or within any territory not organized with a legislative body

(c) Omitted

(d) The term ``Commission'' means the Consumer Product Safety Commission

(e) The term ``person'' includes an individual, partnership, corporation, and association

(f) The term ``hazardous substance'' means

(1)(A) Any substance or mixture of substances which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a **strong sensitizer**, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat, or other means, if such substances or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.

(B) Any substances which the Commission by regulation finds, pursuant to the provisions of section 1262(a) of this title, meet the requirements of subparagraph (1)(A) of this paragraph

(C) Any radioactive substance, if, with respect to such substance as used in a particular class of article or as packaged, the Commission determines by regulation that the substance is sufficiently hazardous to require labeling in accordance with this chapter in order to protect the public health.

(D) Any toy or other article intended for use by children which the Commission by regulation determines, in accordance with section 1262(e) of this title, presents an electrical, mechanical, or thermal hazard

(E) Any solder which has a lead content in excess of 0.2 percent

(2) The term ``hazardous substance'' shall not apply to pesticides subject to the Federal Insecticide, Fungicide, and Rodenticide Act [7 U S C 136 et seq], nor to foods, drugs and cosmetics subject to the Federal Food, Drug, and Cosmetic Act [21 U S C 301 et seq], nor to substances intended for use as fuels when stored in containers and used in the heating, cooking, or refrigeration system of a house, nor to tobacco and tobacco products, but such term shall apply to any article which is not itself a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act but which is a hazardous substance within the meaning of paragraph (1) of this subsection by reason of bearing or containing such a pesticide

(3) The term ``hazardous substance'' shall not include any

source material, special nuclear material, or byproduct material as defined in the Atomic Energy Act of 1954, as amended [42 U.S.C. 2011 et seq.], and regulations issued pursuant thereto by the Atomic Energy Commission.

(g) The term ``toxic'' shall apply to any substance (other than a radioactive substance) which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface.

(h)(1) The term ``highly toxic'' means any substance which falls within any of the following categories: (a) Produces death within fourteen days in half or more than half of a group of ten or more laboratory white rats each weighing between two hundred and three hundred grams, at a single dose of fifty milligrams or less per kilogram of body weight, when orally administered, or (b) produces death within fourteen days in half or more than half of a group of ten or more laboratory white rats each weighing between two hundred and three hundred grams, when inhaled continuously for a period of one hour or less at an atmospheric concentration of two hundred parts per million by volume or less of gas or vapor or two milligrams per liter by volume or less of mist or dust, provided such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner, or (c) produces death within fourteen days in half or more than half of a group of ten or more rabbits tested in a dosage of two hundred milligrams or less per kilogram of body weight, when administered by continuous contact with the bare skin for twenty-four hours or less.

(2) If the Commission finds that available data on human experience with any substance indicate results different from those obtained on animals in the above-named dosages or concentrations, the human data shall take precedence.

(i) The term ``corrosive'' means any substance which in contact with living tissue will cause destruction of tissue by chemical action, but shall not refer to action on inanimate surfaces.

(j) The term ``irritant'' means any substance not corrosive within the meaning of subparagraph (i) of this section which on immediate, prolonged, or repeated contact with normal living tissue will induce a local inflammatory reaction.

(k) The term ``**strong sensitizer**'' means a substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance and which is designated as such by the Commission. Before designating any substance as a **strong sensitizer**, the Commission, upon consideration of the frequency of occurrence and severity of the reaction, shall find that the substance has a significant potential for causing hypersensitivity.

(l)(1) The terms ``extremely flammable'', ``flammable'', and ``combustible'' as applied to any substance, liquid, solid, or the content of a self-pressurized container shall be defined by regulations issued by the Commission.

(2) The test methods found by the Commission to be generally applicable for defining the flammability or combustibility characteristics of any such substance shall also be specified in such regulations.

(3) In establishing definitions and test methods related to flammability and combustibility, the Commission shall consider the existing definitions and test methods of other Federal agencies involved in the regulation of flammable and combustible substances in storage, transportation and use; and to the extent possible, shall establish compatible definitions and test methods.

(4) Until such time as the Commission issues a regulation under paragraph (1) defining the term ``combustible'' as applied to liquids, such term shall apply to any liquid which has a flash point above eighty degrees Fahrenheit to and including one hundred and fifty degrees, as

determined by the Tagliabue Open Cup Tester.

(m) The term ``radioactive substance'' means a substance which emits ionizing radiation

(n) The term ``label'' means a display of written, printed, or graphic matter upon the immediate container of any substance or, in the case of an article which is unpackaged or is not packaged in an immediate container intended or suitable for delivery to the ultimate consumer, a display of such matter directly upon the article involved or upon a tag or other suitable material affixed thereto, and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears (1) on the outside container or wrapper, if any there be, unless it is easily legible through the outside container or wrapper and (2) on all accompanying literature where there are directions for use, written or otherwise

(o) The term ``immediate container'' does not include package liners

(p) The term ``misbranded hazardous substance'' means a hazardous substance (including a toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted) intended, or packaged in a form suitable, for use in the household or by children, if the packaging or labeling of such substance is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of this title or if such substance, except as otherwise provided by or pursuant to section 1262 of this title, fails to bear a label--

(1) which states conspicuously (A) the name and place of business of the manufacturer, packer, distributor or seller, (B) the common or usual name or the chemical name (if there be no common or usual name) of the hazardous substance or of each component which contributes substantially to its hazard, unless the Commission by regulation permits or requires the use of a recognized generic name, (C) the signal word ``DANGER'' on substances which are extremely flammable, corrosive, or highly toxic, (D) the signal word ``WARNING'' or ``CAUTION'' on all other hazardous substances, (E) an affirmative statement of the principal hazard or hazards, such as ``Flammable'', ``Combustible'', ``Vapor Harmful'', ``Causes Burns'', ``Absorbed Through Skin'', or similar wording descriptive of the hazard, (F) precautionary measures describing the action to be followed or avoided, except when modified by regulation of the Commission pursuant to section 1262 of this title, (G) instruction, when necessary or appropriate, for first-aid treatment; (H) the word ``poison'' for any hazardous substance which is defined as ``highly toxic'' by subsection (h) of this section, (I) instructions for handling and storage of packages which require special care in handling or storage, and (J) the statement (i) ``Keep out of the reach of children'' or its practical equivalent, or, (ii) if the article is intended for use by children and is not a banned hazardous substance, adequate directions for the protection of children from the hazard, and

(2) on which any statements required under subparagraph (1) of this paragraph are located prominently and are in the English language in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the label

The term ``misbranded hazardous substance'' also includes a household substance as defined in section 1471(2)(d) of this title if it is a substance described in paragraph (1) of subsection (f) of this section and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of this title.

(q)(1) The term ``banned hazardous substance'' means (A) any toy, or other article intended for use by children, which is a hazardous

substance, or which bears or contains 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 (B) any hazardous substance intended, or packaged in a form suitable, for use in the household, which the Commission by regulation classifies as a ``banned hazardous substance'' on the basis of a finding that, notwithstanding such cautionary labeling as is or may be required under this chapter for that substance, the degree or nature of the hazard involved in the presence or use of such substance in households is such that the objective of the protection of 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 Provided, That the Commission, by regulation, (i) shall exempt from clause (A) of this paragraph articles, such as chemical sets, which by reason of their functional purpose require the inclusion of the hazardous substance involved or necessarily present an electrical, mechanical, or thermal hazard, and which bear labeling giving adequate directions and warnings for safe use and are intended for use by children who have attained sufficient maturity, and may reasonably be expected, to read and heed such directions and warnings, and (ii) shall exempt from clause (A), and provide for the labeling of, common fireworks (including toy paper caps, cone fountains, cylinder fountains, whistles without report, and sparklers) to the extent that it determines that such articles can be adequately labeled to protect the purchasers and users thereof

(2) Proceedings for the issuance, amendment, or repeal of regulations pursuant to clause (B) of paragraph (1) of this subsection shall be governed by the provisions of sections 371(e), (f), and (g) of title 21 Provided, That if the Commission finds that the distribution for household use of the hazardous substance involved presents an imminent hazard to the public health, it may by order published in the Federal Register give notice of such finding, and thereupon such substance when intended or offered for household use, or when so packaged as to be suitable for such use, shall be deemed to be a ``banned hazardous substance'' pending the completion of proceedings relating to the issuance of such regulations.

(r) An article may be determined to present an electrical hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture may cause personal injury or illness by electric shock

(s) An article may be determined to present a mechanical hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness (1) from fracture, fragmentation, or disassembly of the article, (2) from propulsion of the article (or any part or accessory thereof), (3) from points or other protrusions, surfaces, edges, openings, or closures, (4) from moving parts, (5) from lack of insufficiency of controls to reduce or stop motion, (6) as a result of self-adhering characteristics of the article, (7) because the article (or any part or accessory thereof) may be aspirated or ingested, (8) because of instability, or (9) because of any other aspect of the article's design or manufacture.

(t) An article may be determined to present a thermal hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness because of heat as from heated parts, substances, or surfaces

(Pub L 86-613, Sec. 2, July 12, 1960, 74 Stat 372, Pub L 89-756, Secs 2(a)-(c), 3(a), Nov. 3, 1966, 80 Stat 1303, 1304, Pub. L. 91-113, Secs 2(a), (c), (d), 3, Nov. 6, 1969, 83 Stat 187-189, Pub. L 91-601, Sec 6(a), formerly Sec. 7(a), Dec 30, 1970, 84 Stat 1673, renumbered Pub. L 97-35, title XII, Sec 1205(c), Aug 13, 1981, 95 Stat. 716, Pub. L 92-516, Sec. 3(1), Oct 21, 1972, 86 Stat. 998, Pub. L. 92-573, Sec 30(a), Oct 27, 1972, 86 Stat 1231, Pub L 94-284, Sec. 3(c), May

11, 1976, 90 Stat 503; Pub L 95-631, Sec. 9, Nov 10, 1978, 92 Stat. 3747, Pub L 99-339, title I, Sec 109(d)(1), June 19, 1986, 100 Stat. 653)

References in Text

This chapter, referred to in text, was in the original ``this Act'', meaning Pub L 86-613. For complete classification of this Act to the Code, see Short Title note set out below and Tables

For definition of Canal Zone, referred to in subsec. (a), see section 3602(b) of Title 22, Foreign Relations and Intercourse

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in subsec (f)(2), is act June 25, 1947, ch 125, as amended generally by Pub L. 92-516, Oct 21, 1972, 86 Stat 973, which is classified generally to subchapter II (Sec 136 et seq) of chapter 6 of Title 7, Agriculture For complete classification of this Act to the Code, see Short Title note set out under section 136 of Title 7 and Tables.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec (f)(2), is act June 25, 1938, ch 675, 52 Stat 1040, as amended, which is classified generally to chapter 9 (Sec 301 et seq.) of Title 21, Food and Drugs For complete classification of this Act to the Code, see section 301 of Title 21 and Tables

The Atomic Energy Act of 1954, as amended, referred to in subsec (f)(3), is act Aug. 1, 1946, ch 724, as added by act Aug 30, 1954, ch. 1073, Sec 1, 68 Stat 921, and amended, which is classified generally to chapter 23 (Sec 2011 et seq) of Title 42, The Public Health and Welfare For complete classification of this Act to the Code, see Short Title note set out under section 2011 of Title 42 and Tables.

Codification

Subsec (c), which read ``The term `Department' means the Department of Health, Education, and Welfare'' has been omitted from the Code in view of the transfer of functions of the Secretary of Health, Education, and Welfare under this chapter to the Consumer Product Safety Commission pursuant to section 30(a) of Pub L. 92-573 which is classified to section 2079(a) of this title

Amendments

1986--Subsec (f)(1)(E) Pub L 99-339 added subpar (E)

1978--Subsec (l). Pub L 95-631 transferred the duties hereunder to the Commission from the Secretary, incorporated in provisions designated par. (1) existing text, authorized regulations to be applicable to liquids, and struck out definition of ``extremely flammable'' as substance with flash point at or below twenty degrees Fahrenheit and ``flammable'' as substance with a flash point of above twenty degrees to and including eighty degrees Fahrenheit, as determined by the Tagliabue Open Cup Tester, incorporated in provisions designated par (2) existing text extended to liquids covered in term ``substance'', added par (3), and incorporated in provisions designated par. (4) existing text applicable until superseded by regulation.

1976--Subsec (f)(2) Pub L 94-284 inserted ``nor to tobacco and tobacco products,'' after ``or refrigeration system of a house''.

1972--Subsec (f)(2) Pub L 92-516 substituted ``pesticides'' for ``economic poisons'' and ``a pesticide'' for ``an economic poison'' wherever appearing

1970--Subsec (p). Pub L. 91-601 substituted in text preceding par (1) ``if the packaging or labeling of such substance is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of this title or if such substance'' for ``which substance'' and inserted following and below par. (2) provision including in ``misbranded hazardous substance'' a household substance as defined in section

1471(2)(D) of this title if it is a substance described in par. (1) of subsec (f) of this section and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of this title

1969--Subsec (f)(1)(A) Pub L 91-113, Sec 3(a), inserted ``or combustible'' after ``is flammable''

Subsec (f)(1)(D) Pub L 91-113, Sec 2(a), added subsec (f)(1)(D)

Subsec (l). Pub L 91-113, Sec 3(b), inserted definition of term ``combustible'' and expanded references to ``flammability'' and ``flammable'' to include ``combustibility'' and ``combustible'', respectively

Subsec (p)(1)(E). Pub L 91-113, Sec 3(c), inserted ``Combustible'' to the enumerated affirmative statements of the principal hazard or hazards required to be stated on the label of a hazardous substance

Subsec (q)(1) Pub L 91-113, Sec. 2(c), inserted ``or necessarily present an electrical, mechanical, or thermal hazard'' after ``hazardous substance involved''.

Subsecs (r) to (t). Pub. L. 91-113, Sec 2(d), added subsecs (r) to (t)

1966--Subsec (f). Pub L 89-756, Sec 2(a), provided that ``hazardous substances'' shall apply to any article which is not itself an economic poison within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act but which is a hazard substance within the meaning of par (1) of this subsec by reason of its bearing or containing an economic poison.

Subsec (n) Pub. L. 89-756, Sec 2(b), enlarged term ``label'' to include, where the article is unpackaged or is packaged in an immediate container not intended or suitable for delivery to the ultimate consumer, a display of written, printed or graphic matter directly upon the article involved or upon a tag or other suitable material affixed thereto

Subsec (p) Pub L 89-756, Sec 2(c), in introductory text preceding par (1) substituted ``misbranded hazardous substance'' for ``misbranded package'' and ``misbranded package of a hazardous substance'' and as so retermed enlarged applicability to include toys and other articles intended for use by children, which are hazardous substances, or which bear or contain hazardous substances when susceptible of access by children, and in par (1), clause (J) inserted further category of ``misbranded hazardous substance'' where the article is intended for use by children and is not a banned hazardous substance and fails to bear a label with adequate directions for the protection of children from the hazard.

Subsec (q) Pub L 89-756, Sec 3(a), added subsec (q).

Effective Date of 1986 Amendment

Section 109(d)(3) of Pub L 99-339 provided that. ``The amendments made by this subsection [amending this section and section 1263 of this title] shall become effective 24 months after the enactment of this Act [June 19, 1986] ''

Effective Date of 1972 Amendment

Amendment by Pub L 92-516 effective at close of Oct 21, 1972, except if regulations are necessary for the implementation of any provision that becomes effective on Oct. 21, 1972, and continuation in effect of subchapter I of chapter 6 of title 7, and regulations thereunder, relating to the control of economic poisons, as in existence prior to Oct 21, 1972, until superseded by provisions of Pub L 92-516 and regulations thereunder, see section 4 of Pub L 92-516, set out as

a note under section 136 of Title 7, Agriculture

Effective Date of 1970 Amendment

Amendment by Pub L 91-601 effective Dec 30, 1970, and regulations establishing special packaging standards effective no sooner than 180 days or later than one year from date regulations are final, or an earlier date published in Federal Register, see section 8 of Pub L 91-601, set out as a note under section 1471 of this title

Effective Date of 1969 Amendment

Section 5 of Pub. L. 91-113 provided that: ``The amendments made by this Act [see Short Title of 1969 Amendment note below] shall take effect on the sixtieth day following the date of the enactment of this Act [Nov 6, 1969].''

Effective Date

Pub. L 86-613, Sec 17, formerly Sec 16, July 12, 1960, 74 Stat. 380, renumbered Pub L 91-113, Sec 4(a), Nov 6, 1969, 83 Stat 189, provided that ``This Act [enacting this chapter and repealing sections 401 to 411 of this title] shall take effect upon the date of its enactment [July 12, 1960], but no penalty or condemnation shall be enforced for any violation of this Act which occurs--

``(a) prior to the expiration of the sixth calendar month after the month in which this Act is enacted [July 1960], or

``(b) prior to the expiration of such additional period or periods, ending not more than eighteen months after the month of enactment of this Act [July 1960], as the Secretary may prescribe on the basis of a finding that conditions exist which necessitate the prescribing of such additional period or periods Provided, That the Secretary may limit the application of such additional period or periods to violations related to specified provisions of this Act, or to specified kinds of hazardous substances or packages thereof ''

Short Title of 1994 Amendment

Pub L. 103-267, Sec 1, June 16, 1994, 108 Stat. 722, provided that ``This Act [enacting sections 1278 and 6001 to 6006 of this title and provisions set out as notes under this section and sections 1278, 2064, and 6001 of this title] may be cited as the `Child Safety Protection Act' ''

Short Title of 1984 Amendment

Pub L 98-491, Sec 1, Oct 17, 1984, 98 Stat 2269, provided ``That this Act [amending section 1274 of this title] may be cited as the `Toy Safety Act of 1984' ''

Short Title of 1969 Amendment

Section 1 of Pub L. 91-113 provided that: ``This Act [enacting section 1274 of this title, amending this section and section 1262 of this title, enacting provisions set out as notes under this section, and amending provisions set out as notes under this section and section 401 of this title] may be cited as the `Child Protection and Toy Safety Act of 1969' ''

Short Title of 1966 Amendment

Section 1 of Pub L 89-756 provided that ``This title [amending this section, sections 1262, 1263, 1264, 1265, 1273 of this title, and provisions set out as a note under this section] may be cited as the `Child Protection Act of 1966' ''

Short Title

Section 1 of Pub L 86-613, as amended by section 5 of Pub L 89-756, provided ``This Act [enacting this chapter, repealing sections 401 to 411 of this title, and enacting notes set out under this section], may be cited as the `Federal Hazardous Substances Act' ''

Separability

Pub L 86-613, Sec 16, formerly Sec 15, July 12, 1960, 74 Stat 380, renumbered Pub L. 91-113, Sec 4(a), Nov 6, 1969, 83 Stat. 189, provided that ``If any provision of this Act [enacting this chapter and repealing sections 401 to 411 of this title] is declared unconstitutional, or the applicability thereof to any person or circumstance is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby ''

Transfer of Functions

In subsec (d), ``Commission'' substituted for ``Secretary'' and ``Consumer Product Safety Commission'' substituted for ``Secretary of Health, Education, and Welfare'' and in subsecs (f)(1)(B) to (D), (h)(2), (k), (p)(1), and (q), ``Commission'' substituted for ``Secretary'' and ``it'' substituted for ``he'' wherever appearing pursuant to section 30(a) of Pub L 92-573, which is classified to section 2079(a) of this title and which transferred functions of Secretary of Health, Education, and Welfare under this chapter to Consumer Product Safety Commission

Atomic Energy Commission abolished and functions transferred by sections 5814 and 5841 of Title 42, The Public Health and Welfare See, also, Transfer of Functions notes set out under those sections

Effect Upon Federal and State Law

Pub L 86-613, Sec 18, formerly Sec 17, July 12, 1960, 74 Stat 380, as amended by Pub L 89-756, Sec. 4(a), Nov 3, 1966, 80 Stat. 1305, renumbered and amended by Pub. L. 91-113, Sec 4(a), (b)(1), Nov. 6, 1969, 83 Stat 189, 190, Pub L 94-284, Sec 17(a), May 11, 1976, 90 Stat 510, provided that

``(a) Nothing in this act [enacting this chapter and repealing sections 401 to 411 of this title] shall be construed to modify or affect the provisions of the Flammable Fabrics Act, as amended (15 U S C 1191 to 1200) [sections 1191 to 1204 of this title], or any regulations promulgated thereunder, or of chapter 39, title 18, United States Code, as amended (18 U S C 831 et seq.), or any regulations promulgated thereunder or under sections 204(a)(2) and 204(a)(3) of the Interstate Commerce Act, as amended [section 31502 of Title 49, Transportation] (relating to the transportation of dangerous substances and explosives by surface carriers), or of section 1716, title 18, United States Code, or any regulations promulgated thereunder (relating to mailing of dangerous substances); or of section 902 [section 1472 of

former Title 49] or regulations promulgated under section 601 of the Federal Aviation Act of 1958 [section 1421 of former Title 49] (relating to transportation of dangerous substances and explosives in aircraft), or of the Federal Food, Drug, and Cosmetic Act [chapter 9 of Title 21, Food and Drugs], or of the Public Health Service Act [chapter 6A of Title 42, The Public Health and Welfare]; or of the Federal Insecticide, Fungicide, and Rodenticide Act [section 136 et seq of Title 7, Agriculture], or of the Dangerous Drug Act for the District of Columbia (70 Stat 612), or the Act entitled `An Act to regulate the practice of pharmacy and the sale of poisons in the District of Columbia, and for other purposes', approved May 7, 1906 (34 Stat 175), as amended, or of any other Act of Congress, except as specified in section 19 [set out as a note under sections 401 to 411 of this title]

``(b)(1)(A) Except as provided in paragraphs (2) and (3), if a hazardous substance or its packaging is subject to a cautionary labeling requirement under section 2(p) or 3(b) [subsec (p) of this section or section 1262(b) of this title] designed to protect against a risk of illness or injury associated with the substance, no State or political subdivision of a State may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement under section 2(p) or 3(b) [subsec (p) of this section or section 1262(b) of this title].

``(B) Except as provided in paragraphs (2), (3), and (4), if under regulations of the Commission promulgated under or for the enforcement of section 2(q) [subsec. (q) of this section] a requirement is established to protect against a risk of illness or injury associated with a hazardous substance, no State or political subdivision of a State may establish or continue in effect a requirement applicable to such substance and designed to protect against the same risk of illness or injury unless such requirement is identical to the requirement established under such regulations

``(2) The Federal Government and the government of any State or political subdivision of a State may establish and continue in effect a requirement applicable to a hazardous substance for its own use (or to the packaging of such a substance) which requirement is designed to protect against a risk of illness or injury associated with such substance and which is not identical to a requirement described in paragraph (1) applicable to such substance (or packaging) and designed to protect against the same risk of illness or injury if the Federal, State, or political subdivision requirement provides a higher degree of protection from such risk of illness or injury than the requirement described in paragraph (1).

``(3)(A) Upon application of a State or political subdivision of a State, the Commission may, by regulation promulgated in accordance with subparagraph (B), exempt from paragraph (1), under such conditions as may be prescribed in such regulation, any requirement of such State or political subdivision designed to protect against a risk of illness or injury associated with a hazardous substance if--

``(i) compliance with the requirement would not cause the hazardous substance (or its packaging) to be in violation of the applicable requirement described in paragraph (1), and

``(ii) the State or political subdivision requirement (I) provides a significantly higher degree of protection from such risk of illness or injury than the requirement described in paragraph (1), and (II) does not unduly burden interstate commerce

In determining the burden, if any, of a State or political subdivision requirement on interstate commerce the Commission shall consider and make appropriate (as determined by the Commission in its discretion) findings on the technological and economic feasibility of complying with such requirement, the cost of complying with such requirement, the geographic distribution of the substance to which the requirement would apply, the probability of other States or political subdivisions

applying for an exemption under this paragraph for a similar requirement, and the need for a national, uniform requirement under this Act [this chapter] for such substance (or its packaging)

``(B) A regulation under subparagraph (A) granting an exemption for a requirement of a State or political subdivision of a State may be promulgated by the Commission only after it has provided, in accordance with section 553(b) of title 5, United States Code, notice with respect to the promulgation of the regulation and has provided opportunity for the oral presentation of views respecting its promulgation.

``(4) Paragraph (1)(B) does not prohibit a State or a political subdivision of a State from establishing or continuing in effect a requirement which is designed to protect against a risk of illness or injury associated with fireworks devices or components thereof and which provides a higher degree of protection from such risk of illness or injury than a requirement in effect under a regulation of the Commission described in such paragraph

``(5) As used in this subsection, the term `Commission' means the Consumer Product Safety Commission ''

Small Balls as Banned Hazardous Substances

Pub L 103-267, title I, Sec 101(b), June 16, 1994, 108 Stat 725, provided that. ``A small ball--

``(1) intended for children under the age of 3 years of age, and

``(2) with a diameter of 1 75 inches or less,

shall be considered a banned hazardous substance under section 2(q) of the Federal Hazardous Substances Act (15 U S C. 1261(q)).''

[Section 101(b) of Pub L. 103-267, set out above, effective Jan. 1, 1995, see section 101(d) of Pub. L 103-267, set out as an Effective Date note under section 1278 of this title]

Section Referred to in Other Sections

This section is referred to in sections 1262, 1275, 1276, 1278, 1471, 2080 of this title.

16 CFR 1500.3

AUTHORITY 15 U S C 1261–1278

SOURCE 38 FR 27012 Sept 27 1973 unless otherwise noted

§ 1500 1 Scope of subchapter

Set forth in this subchapter C are the regulations of the Consumer Product Safety Commission issued pursuant to and for the implementation of the Federal Hazardous Substances Act as amended (see § 1500 3(a)(1))

§ 1500 2 Authority

Authority under the Federal Hazardous Substances Act is vested in the Consumer Product Safety Commission by section 30(a) of the Consumer Product Safety Act (15 U S C 2079(a))

§ 1500 3 Definitions

(a) *Certain terms used in this part* As used in this part

(1) *Act* means the Federal Hazardous Substances Act (Pub L 86–613 74 Stat 372–81 (15 U S C 1261–74)) as amended by

(i) The Child Protection Act of 1966 (Pub L 89–756, 80 Stat 1303–05)

(ii) The Child Protection and Toy Safety Act of 1969 (Pub L 91–113 83 Stat 187–90)

(iii) The Poison Prevention Packaging Act of 1970 (Pub L 91–601 84 Stat 1670–74)

(2) *Commission* means the Consumer Product Safety Commission established May 14 1973 pursuant to provisions of the Consumer Product Safety Act (Pub L 92–573 86 Stat 1207–33 (15 U S C 2051–81))

(b) *Statutory definitions* Except for the definitions given in section 2 (c) and (d) of the act which are obsolete the definitions set forth in section 2 of the act are applicable to this part and are repeated for convenience as follows (some of these statutory definitions are interpreted supplemented or provided with alternatives in paragraph (c) of this section)

(1) *Territory* means any territory or possession of the United States including the District of Columbia and the Commonwealth of Puerto Rico but excluding the Canal Zone

(2) *Interstate commerce* means (i) commerce between any State or territory and any place outside thereof and (ii) commerce within the District of Columbia or within any territory not organized with a legislative body

(3) *Person* includes an individual partnership corporation and association

(4)(i) *Hazardous substance* means

(A) Any substance or mixture of substances which is toxic corrosive an irritant a strong sensitizer flammable or combustible, or generates pressure through decomposition, heat or other means if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use including reasonably foreseeable ingestion by children

(B) Any substance which the Commission by regulation finds pursuant to the provisions of section 3(a) of the act meet the requirements of section 2(f)(1)(A) of the act (restated in (A) above)

(C) Any radioactive substance if with respect to such substance as used in a particular class of article or as packaged the Commission determines by regulation that the substance is sufficiently hazardous to require labeling in accordance with the act in order to protect the public health

(D) Any toy or other article intended for use by children which the Commission by regulation determines in accordance with section 3(e) of the act, presents an electrical mechanical or thermal hazard

(ii) *Hazardous substance* shall not apply to pesticides subject to the Federal Insecticide Fungicide and Rodenticide Act to foods, drugs and cosmetics subject to the Federal Food, Drug, and Cosmetic Act, nor to substances intended for use as fuels when stored in containers and used in the heating cooking or refrigeration system of a house "Hazardous substance" shall apply however to any article which is not itself a pesticide within the meaning of the Federal Insecticide Fungicide and Rodenticide Act but which is a hazardous substance within the meaning of section 2(f)(1) of the Federal Hazardous Substances Act (restated in paragraph (b)(4)(i) of this section) by reason of bearing or containing such a pesticide

(iii) *Hazardous substance* shall not include any source material special nuclear material or byproduct material as defined in the Atomic Energy Act of 1954 as amended and regulations issued pursuant thereto by the Atomic Energy Commission

(5) *Toxic* shall apply to any substance (other than a radioactive substance) which has the capacity to produce personal injury or illness to man through ingestion inhalation or absorption through any body surface

(6)(i) *Highly toxic* means any substance which falls within any of the following categories

(A) Produces death within 14 days in half or more than half of a group of 10 or more laboratory white rats each weighing between 200 and 300 grams, at a single dose of 50 milligrams or less per kilogram of body weight when orally administered or

(B) Produces death within 14 days in half or more than half of a group of 10 or more laboratory white rats each weighing between 200 and 300 grams when inhaled continuously for a period of 1 hour or less at an atmospheric concentration of 200 parts per million by volume or less of gas or vapor or 2 milligrams per liter by volume or less of mist or dust provided such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner or

(C) Produces death within 14 days in half or more than half of a group of 10 or more rabbits tested in a dosage of 200 milligrams or less per kilogram of body weight, when administered by continuous contact with the bare skin for 24 hours or less

(ii) If the Commission finds that available data on human experience with any substance indicate results different from those obtained on animals in the dosages and concentrations specified in paragraph (b)(6)(i) of this section the human data shall take precedence

(7) *Corrosive* means any substance which in contact with living tissue will cause destruction of tissue by chemical action but shall not refer to action on inanimate surfaces

(8) *Irritant* means any substance not corrosive within the meaning of section 2(i) of the act (restated in paragraph (b)(7) of this section) which on immediate prolonged or repeated contact with normal living tissue will induce a local inflammatory reaction

(9) *Strong sensitizer* means a substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance and which is designated as such by the Commission Before designating any substance as a strong sensitizer, the Commission, upon consideration of the frequency of occurrence and severity of the reaction, shall find that the substance has a significant potential for causing hypersensitivity

(10) The terms *extremely flammable flammable,* and *combustible* as they apply to any substances liquid solid or the contents of any self-pressurized container, are defined by regulations issued by the Commission and published at § 1500 3(c)(6)

(11) *Radioactive substance* means a substance which emits ionizing radiation

(12) *Label* means a display of written printed or graphic matter upon the immediate container of any substance or in the cases of an article which is unpackaged or is not packaged in an immediate container intended or suitable for delivery to the ultimate consumer a display of such matter directly upon the article involved or upon a tag or other suitable material affixed thereto A requirement made by or under authority of the act that any word statement or other information appear on the label shall not be considered to be complied with unless such word statement, or other information also appears (i) on the outside container or wrapper, if any there be, unless it is easily legible through the outside container or wrapper and (ii) on all accompanying literature where there are directions for use written or otherwise

(13) *Immediate container* does not include package liners

(14) *Misbranded hazardous substance* means a hazardous substance (including a toy, or other article intended for use by children, which is a hazardous substance or which bears or contains a hazardous substance in such manner as

to be susceptible of access by a child to whom such toy or other article is entrusted) intended, or packaged in a form suitable for use in the household or by children if the packaging or labeling of such substance is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970 or if such substance except as otherwise provided by or pursuant to section 3 of the act (Federal Hazardous Substances Act) fails to bear a label

(i) Which states conspicuously

(A) The name and place of business of the manufacturer packer distributor or seller

(B) The common or usual name or the chemical name (if there be no common or usual name) of the hazardous substance or of each component which contributes substantially to its hazard unless the Commission by regulation permits or requires the use of a recognized generic name,

(C) The signal word DANGER on substances which are extremely flammable corrosive or highly toxic

(D) The signal word WARNING or CAUTION ' on all other hazardous substances,

(E) An affirmative statement of the principal hazard or hazards such as Flammable Combustible Vapor Harmful, Causes Burns Absorbed Through Skin or similar wording descriptive of the hazard,

(F) Precautionary measures describing the action to be followed or avoided except when modified by regulation of the Commission pursuant to section 3 of the act

(G) Instruction when necessary or appropriate for first-aid treatment,

(H) The word *Poison* for any hazardous substance which is defined as highly toxic" by section 2(h) of the act (restated in paragraph (b)(6) of this section)

(I) Instructions for handling and storage of packages which require special care in handling or storage and

(J) The statement (*1*) Keep out of the reach of children or its practical equivalent or (*2*) if the article is intended for use by children and is not a banned hazardous substance, adequate directions for the protection of children from the hazard and

(ii) On which any statements required under section 2(p)(1) of the act (restated in paragraph (b)(14)(i) of this section) are located prominently and are in the English language in conspicuous and legible type in contrast by typography layout or color with other printed matter on the label

Misbranded hazardous substance also means a household substance as defined in section 2(2)(D) of the Poison Prevention Packaging Act of 1970 if it is a substance described in section 2(f)(1) of the Federal Hazardous Substances Act (restated in paragraph (b)(4)(i)(A) of this section) and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970

(15)(i) *Banned hazardous substance* means

(A) Any toy or other article intended for use by children which is a hazardous substance, or which bears or contains 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

(B) Any hazardous substance intended or packaged in a form suitable for use in the household which the Commission by regulation classifies as a banned hazardous substance ' on the basis of a finding that, notwithstanding such cautionary labeling as is or may be required under the act for that substance the degree or nature of the hazard involved in the presence or use of such substance in households is such that the objective of the protection of 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, *Provided,* That the Commission by regulation (*1*) shall exempt from section 2(q)(1)(A) of the act (restated in paragraph (b)(15)(i)(A) of this section) articles such as chemistry sets which by reason of their functional purpose require the inclusion of the hazardous substance involved or necessarily present an electrical, mechanical or thermal hazard, and which bear labeling giving adequate directions and warnings for safe

use and are intended for use by children who have attained sufficient maturity and may reasonably be expected to read and heed such directions and warnings and (*2*) shall exempt from section 2(q)(1)(A) of the act (restated in paragraph (b)(15)(i)(A) of this section), and provide for the labeling of, common fireworks (including toy paper caps cone fountains cylinder fountains whistles without report, and sparklers) to the extent that the Commission determines that such articles can be adequately labeled to protect the purchasers and users thereof

(ii) Proceedings for the issuance amendment or repeal of regulations pursuant to section 2(q)(1)(B) of the act (restated in paragraph (b)(15)(i)(B) of this section) shall be governed by the provisions of section 701 (e) (f) and (g) of the Federal Food Drug and Cosmetic Act *Provided* That if the Commission finds that the distribution for household use of the hazardous substance involved presents an imminent hazard to the public health the Commission may by order published in the FEDERAL REGISTER give notice of such finding and thereupon such substance when intended or offered for household use or when so packaged as to be suitable for such use shall be deemed to be a banned hazardous substance pending the completion of proceedings relating to the issuance of such regulations

(16) Electrical hazard —an article may be determined to present an electrical hazard if in normal use or when subjected to reasonably foreseeable damage or abuse its design or manufacture may cause personal injury or illness by electric shock

(17) Mechanical hazard —an article may be determined to present a mechanical hazard if in normal use or when subjected to reasonably foreseeable damage or abuse its design or manufacture presents an unreasonable risk of personal injury or illness

(i) From fracture fragmentation or disassembly of the article

(ii) From propulsion of the article (or any part or accessory thereof),

(iii) From points or other protrusions surfaces edges openings or closures,

(iv) From moving parts,

(v) From lack or insufficiency of controls to reduce or stop motion

(vi) As a result of self-adhering characteristics of the article,

(vii) Because the article (or any part or accessory thereof) may be aspirated or ingested

(viii) Because of instability or

(ix) Because of any other aspect of the article s design or manufacture

(18) Thermal hazard '—an article may be determined to present a thermal hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse its design or manufacture presents an unreasonable risk of personal injury or illness because of heat as from heated parts substances or surfaces

(c) *Certain statutory definitions interpreted supplemented or provided with alternatives* The following items interpret supplement, or provide alternatives to definitions set forth in section 2 of the act (and restated in paragraph (b) of this section)

(1) To provide flexibility as to the number of animals tested the following is an alternative to the definition of highly toxic in section 2(h) of the act (and paragraph (b)(6) of this section), *Highly toxic* means

(i) A substance determined by the Commission to be highly toxic on the basis of human experience and/or

(ii) A substance that produces death within 14 days in half or more than half of a group of

(A) White rats (each weighing between 200 and 300 grams) when a single dose of 50 milligrams or less per kilogram of body weight is administered orally

(B) White rats (each weighing between 200 and 300 grams) when a concentration of 200 parts per million by volume or less of gas or vapor, or 2 milligrams per liter by volume or less of mist or dust, is inhaled continuously for 1 hour or less, if such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner, and/or

(C) Rabbits (each weighing between 2 3 and 3 0 kilograms) when a dosage of 200 milligrams or less per kilogram of body weight is administered by continuous contact with the bare skin for 24

hours or less by the method described in § 1500 40

The number of animals tested shall be sufficient to give a statistically significant result and shall be in conformity with good pharmacological practices

(2) To give specificity to the definition of toxic in section 2(g) of the act (and restated in paragraph (b)(5) of this section), the following supplements that definition The following categories are not intended to be inclusive

(i) *Acute toxicity Toxic* means any substance that produces death within 14 days in half or more than half of a group of

(A) White rats (each weighing between 200 and 300 grams) when a single dose of from 50 milligrams to 5 grams per kilogram of body weight is administered orally Substances falling in the toxicity range between 500 milligrams and 5 grams per kilogram of body weight will be considered for exemption from some or all of the labeling requirements of the act, under § 1500 82 upon a showing that such labeling is not needed because of the physical form of the substances (solid, a thick plastic, emulsion, etc) the size or closure of the container human experience with the article or any other relevant factors,

(B) White rats (each weighing between 200 and 300 grams) when an atmospheric concentration of more than 200 parts per million but not more than 20 000 parts per million by volume of gas or vapor or more than 2 but not more than 200 milligrams per liter by volume of mist or dust is inhaled continuously for 1 hour or less if such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner and/or

(C) Rabbits (each weighing between 2 3 and 3 0 kilograms) when a dosage of more than 200 milligrams but not more than 2 grams per kilogram of body weight is administered by continuous contact with the bare skin for 24 hours by the method described in § 1500 40

The number of animals tested shall be sufficient to give a statistically significant result and shall be in conformity with good pharmacological practices

Toxic also applies to any substance that is toxic (but not highly toxic ') on the basis of human experience

(ii) *Chronic toxicity* A substance is toxic because it presents a chronic hazard if it falls into one of the following categories (For additional information see the chronic toxicity guidelines at 16 CFR 1500 135)

(A) *For Carcinogens* A substance is toxic if it is or contains a known or probable human carcinogen

(B) *For Neurotoxicological Toxicants* A substance is toxic if it is or contains a known or probable human neurotoxin

(C) *For Developmental or Reproductive Toxicants* A substance is toxic if it is or contains a known or probable human developmental or reproductive toxicant

(3) The definition of *corrosive* in section 2(i) of the act (restated in paragraph (b)(7) of this section) is interpreted to also mean the following *Corrosive* means a substance that causes visible destruction or irreversible alterations in the tissue at the site of contact A test for a corrosive substance is whether, by human experience such tissue destruction occurs at the site of application A substance would be considered corrosive to the skin if when tested on the intact skin of the albino rabbit by the technique described in § 1500 41 the structure of the tissue at the site of contact is destroyed or changed irreversibly in 24 hours or less Other appropriate tests should be applied when contact of the substance with other than skin tissue is being considered

(4) The definition of *irritant* in section 2(j) of the act (restated in paragraph (b)(8) of this section) is supplemented by the following *Irritant* includes "primary irritant to the skin ' as well as substances irritant to the eye or to mucous membranes *Primary irritant* means a substance that is not corrosive and that human experience data indicate is a primary irritant and/or means a substance that results in an empirical score of five or more when tested by the method described in § 1500 41 *Eye irritant* means a substance that human experience data indicate is an irritant to the eye and/or means a substance for which a positive test is obtained when tested by the method described in § 1500 42

(5) The definition of *strong sensitizer* in section 2(k) of the Federal Hazardous Substances Act (restated in 16 CFR 1500 3(b)(9)) is supplemented by the following definitions

(i) *Sensitizer* A *sensitizer* is a substance that will induce an immunologically-mediated (allergic) response including allergic photosensitivity This allergic reaction will become evident upon reexposure to the same substance Occasionally a sensitizer will induce and elicit an allergic response on first exposure by virtue of active sensitization

(ii) *Strong* In determining that a substance is a strong sensitizer the Commission shall consider the available data for a number of factors These factors should include any or all of the following (if available) Quantitative or qualitative risk assessment frequency of occurrence and range of severity of reactions in healthy or susceptible populations the result of experimental assays in animals or humans (considering dose-response factors) with human data taking precedence over animal data other data on potency or bioavailability of sensitizers data on reactions to a cross-reacting substance or to a chemical that metabolizes or degrades to form the same or a cross-reacting substance the threshold of human sensitivity, epidemiological studies case histories occupational studies, and other appropriate *in vivo* and *in vitro* test studies

(iii) *Severity of reaction* The minimal severity of reaction for the purpose of designating a material as a strong sensitizer is a clinically important allergic reaction For example strong sensitizers may produce substantial illness including any or all of the following physical discomfort distress hardship and functional or structural impairment These may but not necessarily require medical treatment or produce loss of functional activities

(iv) *Significant potential for causing hypersensitivity* Significant potential for causing hypersensitivity is a relative determination that must be made separately for each substance It may be based upon the chemical or functional properties of the substance, documented medical evidence of allergic reactions obtained from epidemiological surveys or individual case reports controlled *in vitro* or *in vivo* experimental assays or susceptibility profiles in normal or allergic subjects

(v) *Normal living tissue* The allergic hypersensitivity reaction occurs in normal living tissues, including the skin and other organ systems, such as the respiratory or gastrointestinal tract, either singularly or in combination following sensitization by contact ingestion or inhalation

(6) The Consumer Product Safety Commission by the regulations published in this section defines the terms *extremely flammable, flammable,* and *combustible,* appearing in section 2(1) of the Federal Hazardous Substances Act, as follows

(i) The term *extremely flammable* shall apply to any substance which has a flashpoint at or below 20 °F (−6 7 °C) as determined by the test method described at § 1500 43a except that any mixture having one component or more with a flashpoint higher than 20 °F (−6 7 °C) which comprises at least 99 percent of the total volume of the mixture is not considered to be an extremely flammable substance

(ii) The term *flammable* shall apply to any substance having a flashpoint above 20 °F (−6 7 °C) and below 100 °F (37 8 °C), as determined by the method described at § 1500 43a, except that

(A) Any mixture having one component or more with a flashpoint at or above 100 °F (37 8 °C) which comprises at least 99 percent of the total volume of the mixture is not considered to be a flammable substance, and

(B) Any mixture containing 24 percent or less of water miscible alcohols by volume in aqueous solution is not considered to be flammable if the mixture does not present a significant flammability hazard when used by consumers

(iii) The term *combustible* shall apply to any substance having a flashpoint at or above 100 °F (37 8 °C) to and including 150 °F (65 6 °C) as determined by the test method described at § 1500 43a, except that

(A) Any mixture having one component or more with a flashpoint higher than 150 °F (65 6 °C) which comprises at least 99 percent of the total volume of

the mixture is not considered to be a combustible hazardous substance and

(B) Any mixture containing 24 percent or less of water miscible alcohols by volume in aqueous solution is not considered to be combustible if the mixture does not present a significant flammability hazard when used by consumers

(iv) To determine flashpoint temperatures for purposes of enforcing and administering requirements of the Federal Hazardous Substances Act applicable to "extremely flammable flammable and 'combustible' hazardous substances, the Commission will follow the procedures set forth in § 1500 43a However the Commission will allow manufacturers and labelers of substances and products subject to those requirements to rely on properly conducted tests using the Tagliabue open-cup method which was in effect prior to the issuance of § 1500 43a (as published at 38 FR 27012 September 27 1973 and set forth below) and the defintions of the terms extremely flammable, flammable, and combustible in this section before its amendment (as published at 38 FR 27012 September 27 1983 and amended 38 FR 30105 November 1 1973 set forth in the note following this section) if all of the following conditions are met

(A) The substance or product was subject to and complied with the requirements of the Federal Hazardous Substances Act for extremely flammable "flammable, or combustible hazardous substances before the effective date of § 1500 43a and

(B) No change has been made to the formulation or labeling of such substance or product after the effective date of § 1500 43a prescribing a closed-cup test apparatus and procedure

(v) *Extremely flammable solid* means a solid substance that ignites and burns at an ambient temperature of 80 °F or less when subjected to friction percussion or electrical spark

(vi) *Flammable solid* means a solid substance that when tested by the method described in § 1500 44 ignites and burns with a self-sustained flame at a rate greater than one-tenth of an inch per second along its major axis

(vii) *Extremely flammable contents of self-pressurized container* means contents of a self-pressurized container that when tested by the method described in § 1500 45 a flashback (a flame extending back to the dispenser) is obtained at any degree of valve opening and the flashpoint when tested by the method described in § 1500 43a is less than 20 °F (−6 7 °C)

(viii) *Flammable contents of self-pressurized container* means contents of a self-pressurized container that when tested by the method described in § 1500 45 a flame projection exceeding 18 inches is obtained at full valve opening, or flashback (a flame extending back to the dispenser) is obtained at any degree of valve opening

(7) The definition of *hazardous substance* in section 2(f)(1)(A) of the act (restated in paragraph (b)(4)(i)(A) of this section) is supplemented by the following definitions or interpretations or terms used therein

(i) A substance or mixture of substances that generates pressure through decomposition heat or other means is a hazardous substance

(A) If it explodes when subjected to an electrical spark, percussion, or the flame of a burning paraffin candle for 5 seconds or less

(B) If it expels the closure of its container or bursts its container, when held at or below 130 °F for 2 days or less

(C) If it erupts from its opened container at a temperature of 130 °F or less after having been held in the closed container at 130 °F for 2 days

(D) If it comprises the contents of a self-pressurized container

(ii) *Substantial personal injury or illness* means any injury or illness 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

(iii) *Proximate result* means a result that follows in the course of events without an unforeseeable, intervening, independent cause

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

(8) The definition of radioactive substance in section 2(m) of the act (restated in paragraph (b)(11) of this section) is supplemented by the following *Radioactive substance* means a substance which because of nuclear instability emits electromagnetic and/or particulate radiation capable of producing ions in its passage through matter Source materials special nuclear material and byproduct materials described in section 2(f)(3) of the act are exempt

(9) In the definition of label" in section 2(n) of the act (restated in paragraph (b)(12) of this section) a provision stipulates that words statements or other information required to be on the label must also appear on all accompanying literature where there are directions for use written or otherwise To make this provision more specific, accompanying literature is interpreted to mean any placard pamphlet, booklet book sign or other written printed or graphic matter or visual device that provides directions for use, written or otherwise and that is used in connection with the display, sale demonstration or merchandising of a hazardous substance intended for or packaged in a form suitable for use in the household or by children

(10) The definition of misbranded hazardous substance in section 2(p) of this act (restated in paragraph (b)(14) of this section) is supplemented by the following definitions or interpretations of terms used therein

(i) *Hazardous substances intended or packaged in a form suitable, for use in the household* means any hazardous substance whether or not packaged that under any customary or reasonably foreseeable condition of purchase storage or use may be brought into or around a house, apartment or other place where people dwell or in or around any related building or shed including, but not limited to a garage, carport barn or storage shed The term includes articles, such as polishes or cleaners designed primarily for professional use but which are available in retail stores such as hobby shops for nonprofessional use Also included are items such as antifreeze and radiator cleaners that although principally for car use may be stored in or around dwelling places The term does not include industrial supplies that might be taken into a home by a serviceman An article labeled as and marketed solely for, industrial use does not become subject to this act because of the possibility that an industrial worker may take a supply for his own use Size of unit or container is not the only index of whether the article is suitable for use in or around the household, the test shall be whether under any reasonably foreseeable condition of purchase, storage or use the article may be found in or around a dwelling

(ii) *Conspicuously* in section 2(p)(1) of the act and *prominently* and *conspicuous* in section 2(p)(2) of the act mean that, under customary conditions of purchase, storage and use, the required information shall be visible, noticeable and in clear and legible English Some factors affecting a warning's prominence and conspicuousness are Location size of type and contrast of printing against background Also bearing on the effectiveness of a warning might be the effect of the package contents if spilled on the label

NOTE The definitions of *extremely flammable flammable* and *combustible* hazardous substances set forth above in paragraphs (b)(10) and (c)(6) are effective August 10 1987 The definitions remaining in effect until August 10 1987 as published at 38 FR 27012 Sept 27 1973 and amended at 38 FR 30105, Nov 1 1973 are set forth below Manufacturers and labelers of products subject to the Federal Hazardous Substances Act may continue to use these definitions for labeling of those products under the conditions set forth in § 1500 3(c)(6)(iv) as amended

(b)(10) *Extremely flammable* shall apply to any substance which has a flashpoint at or below 20 °F as determined by the Tagliabue Open Cup Tester *flammable* shall apply to any substance which has a flashpoint of above 20 °F to and including 80 °F as determined by the Tagliabue Open Cup Tester and *combustible* shall apply to any substance which has a flashpoint above 80 °F to and including 150 °F as determined by the Tagliabue Open Cup Tester except that the flammability or combustibility of solids and of the contents of self-pressurized containers shall be determined by methods found by the Commission to be generally applicable to such materials or containers respectively and established by regulations issued by the

16 CFR 1500.13

Commission which regulations shall also define the terms *flammable combustible* and *extremely flammable* in accord with such methods

* * * * *

(c)(6)(i) *Extremely flammable* means any substance that has a flashpoint at or below 20 °F as determined by the method described in § 1500 43

(ii) *Flammable* means any substance that has a flashpoint of above 20 °F to and including 80 °F as determined by the method described in § 1500 43

[38 FR 27012 Sept 27 1973 as amended at 38 FR 30105 Nov 1 1973 49 FR 22465 May 30 1984 51 FR 28536 Aug 8 1986 51 FR 29096, Aug 14 1986 51 FR 30209 Aug 25 1986 57 FR 46669 Oct 9 1992]

§ 1500 4 Human experience with hazardous substances.

(a) 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 When such data give reliable results different from results with animal data the human experience takes precedence

(b) Experience may show that an article is more or less toxic irritant, or corrosive to man than to test animals It may show other factors that are important in determining the degree of hazard to humans represented by the substance For example experience shows that radiator antifreeze is likely to be stored in the household or garage and likely to be ingested in significant quantities by some persons It also shows that a particular substance in liquid form is more likely to be ingested than 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 a liquid

§ 1500 5 Hazardous mixtures.

For a mixture of substances the determination of whether the mixture is a hazardous substance as defined by section 2(f) of the act (repeated in § 1500 3(b)(4)) 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 The mixture itself should be tested

§ 1500.12 Products declared to be hazardous substances under section 3(a) of the act

(a) The Commission 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 reasonably foreseeable handling or use

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

(2) [Reserved]

(b) [Reserved]

§ 1500 13 Listing of "strong sensitizer" substances

On the basis of frequency of occurrence and severity of reaction information the Commission finds that the following substances have a significant potential for causing hypersensitivity and therefore meet the definition for strong sensitizer in section 2(k) of the act (repeated in § 1500 3(b)(9))

(a) Paraphenylenediamine and products containing it

(b) Powdered 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

§ 1500.14 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

Hammond, Rocky X.

From: Rumelt, Daniel L.
Sent: Monday, June 26, 2000 4:24 PM
To: Hammond, Rocky X.
Cc: Chen, Xinxian
Subject: FW: TO OS

Follow Up Flag: Follow up
Flag Status: Flagged

Because this references a petition, and reads more like petition than an incident report, I am forwarding this to you to handle. Thanks.

Dan.

—Original Message—
From: Chen, Xinxian
Sent: Monday, June 26, 2000 3:26 PM
To: Rumelt, Daniel L.
Subject: Refer to ?

6/26/00 1:48:04 PM

Name = Assistant Attorney General Maureen G. Glynn
Address = 150 South main St.
City = Providence
State = RI
Zip = 02903
Email = mglynn@riag.state.ri.us
Telephone = 401-274-4400 x2301
Name of Victim =
Victim's Address =
Victim's City =
Victim's State =
Victim's Zip =
Victim's Telephone =

Incident Description: HO 00-2 Petition Regarding Natural Rubber Latex

As the Health Care Advocate in the Rhode Island Department of Attorney General, we are concerned about allergic reactions to natural rubbber latex. The latex allergic reactions impact not only workers who use natural rubber latex products, but also children. Many toys are made from natural rubber latex but are not labeled further increasing the exposure to natural rubber latex for children. In addition, the medical environment uses latex products, ranging from gloves to tubing, exposing health care workers and children to latex allergens. Ironically, the place where one goes for medical treatment may actually adversely impact the patient allergic to latex because of the unnecessary use of latex products, such as single use latex exam gloves. Unfortuantely, many people are unaware of the potential risks of latex exposure. A declaration that natural rubber latex is a strong sensitizer from the Commission would help education the public about the potential risks of latex allergies and help the public to take measures to educate themselves about the potential

allergic reactions to natural rubber latex.

Sincerely yours,

Maureen G. Glynn
Assistant Attorney General
Health Care Advocate

Victim's age at time of incident =
Victim's sex =
Date of incident =
Product involved =
Product brand name/manufacturer =
Product involved still available = Yes
Product model and serial number =
Date product purchased =