Preventing Contamination by Employees

3-301.11 Preventing Contamination from Hands*

- (A) Food EMPLOYEES shall wash their hands as specified under *§ 2-301.12*.
- (B) *Except when washing fruits and vegetables as specified under* § *3-302.15 or as specified in ¶ (C) of this section,* FOOD EMPLOYEES may not contact exposed, READY-TO-EAT FOOD with their bare hands and shall use suitable UTENSILS such as deli tissue, spatulas, tongs, SINGLE-USE gloves, or dispensing EQUIPMENT.
- (C) *When otherwise* APPROVED, FOOD EMPLOYEES *not serving a* HIGHLY SUSCEPTIBLE POPULATION *may contact exposed,* READY-TO-EAT FOOD *with their bare hands.*
- (D) FOOD EMPLOYEES shall minimize bare hand and arm contact with exposed FOOD that is not in a READY-TO-EAT form.[S]

(**Return to Food Code 2001**)

Amend § 3-304.12 to revise paragraph (F) to read as follows:

3-304.12 In-Use Utensils, Between-Use Storage.

During pauses in FOOD preparation or dispensing, FOOD preparation and dispensing UTENSILS shall be stored:

- (A) Except as specified under ¶ (B) of this section, in the FOOD with their handles above the top of the FOOD and the container;
- (B) In FOOD that is not POTENTIALLY HAZARDOUS with their handles above the top of the FOOD within containers or EQUIPMENT that can be closed, such as bins of sugar, flour, or cinnamon;
- (C) On a clean portion of the FOOD preparation table or cooking EQUIPMENT only if the in-use UTENSIL and the FOOD-CONTACT surface of the FOOD preparation table or cooking EQUIPMENT are cleaned and SANITIZED at a frequency specified under §§ 4-602.11 and 4-702.11;
- (D) In running water of sufficient velocity to flush particulates to the drain, if used with moist FOOD such as ice cream or mashed potatoes;
- (E) In a clean, protected location if the UTENSILS, such as ice scoops, are used only with a FOOD that is not POTENTIALLY HAZARDOUS; or
- (F) In a container of water if the water is maintained at a temperature of at least 57°C (135°F) and the container is cleaned at a frequency specified under Subparagraph 4-602.11(D)(7).

(**Return to Food Code 2001**)

Amend § 3-304.14 to add new paragraph (E) to read as follows:

3-3 PROTECTION FROM CONTAMINATION AFTER RECEIVING

Subparts

Preventing Contamination by Employees

3-301.11 Preventing Contamination from Hands.*

(See Supplement)

- (A) FOOD EMPLOYEES shall wash their hands as specified under § 2-301.12.
- (B) *Except when washing fruits and vegetables as specified under § 3-302.15 or when otherwise* APPROVED, FOOD EMPLOYEES may not contact exposed, READY-TO-EAT FOOD with their bare hands and shall use suitable UTENSILS such as deli tissue, spatulas, tongs, SINGLE-USE gloves, or dispensing EQUIPMENT.
- (C) FOOD EMPLOYEES shall minimize bare hand and arm contact with exposed FOOD that is not in a ready-to-eat form.[S]

3-301.12 Preventing Contamination when Tasting.*

A FOOD EMPLOYEE may not use a UTENSIL more than once to taste FOOD that is to be sold or served.

Preventing Food and Ingredient Contamination

3-302.11 Packaged and Unpackaged Food - Separation, Packaging, and Segregation.*

- (A)FOOD shall be protected from cross contamination by:
    - (1) Separating raw animal FOODS during storage, preparation, holding, and display from:
        - (a) RAW READY-TO-EAT FOOD including other raw animal FOOD such as FISH for sushi or MOLLUSCAN SHELLFISH, or other raw READY-TO-EAT FOOD such as vegetables, and
        - (b) Cooked READY-TO-EAT FOOD;
    - (2) *Except when combined as ingredients*, separating types of raw animal FOODS from each other such as beef, FISH, lamb, pork, and POULTRY during storage, preparation, holding, and display by:
        - (a) Using separate EQUIPMENT for each type, or
        - (b) Arranging each type of FOOD in EQUIPMENT so that cross contamination of one type with another is prevented, and
        - (c) Preparing each type of FOOD at different times or in separate areas;
    - (3) Cleaning EQUIPMENT and UTENSILS as specified under ¶ 4-602.11(A) and sanitizing as specified under § 4-703.11;
    - (4) Except as specified in ¶ (B) of this section, storing the FOOD in packages, covered containers, or wrappings;
    - (5) Cleaning HERMETICALLY SEALED CONTAINERS of FOOD of visible soil before opening;
    - (6) Protecting FOOD containers that are received PACKAGED together in a case or overwrap from cuts when the case or overwrap is opened;
    - (7) Storing damaged, spoiled, or recalled FOOD being held in the FOOD ESTABLISHMENT as specified under § 6-404.11; and
    - (8) Separating fruits and vegetables, before they are washed as specified under § 3-302.15 from READY-TO-EAT FOOD.
- (B) *Subparagraph (A)(4) of this section does not apply to:*
    - *(1) Whole, uncut, raw fruits and vegetables and nuts in the shell, that require peeling or hulling before consumption;*

- (2) PRIMAL CUTS, *quarters, or sides of raw* MEAT *or slab bacon that are hung on clean,* SANITIZED *hooks or placed on clean,* SANITIZED *racks;*
- (3) *Whole, uncut, processed* MEATS *such as country hams, and smoked or cured sausages that are placed on clean,* SANITIZED *racks;*
- (4) FOOD *being cooled as specified under Subparagraph 3-501.15(B)(2); or*
- (5) SHELLSTOCK.

3-302.12 Food Storage Containers, Identified with Common Name of Food.

Working containers holding FOOD or FOOD ingredients that are removed from their original packages for use in the FOOD ESTABLISHMENT, such as cooking oils, flour, herbs, potato flakes, salt, spices, and sugar shall be identified with the common name of the FOOD *except that containers holding* FOOD *that can be readily and unmistakably recognized such as dry pasta need not be identified.*

3-302.13 Pasteurized Eggs, Substitute for Raw Shell Eggs for Certain Recipes.*

Pasteurized EGGS or EGG products shall be substituted for raw shell EGGS in the preparation of FOODS such as Caesar salad, hollandaise or Béarnaise sauce, mayonnaise, eggnog, ice cream, and EGG-fortified BEVERAGES that are not:

- (A) Cooked as specified under Subparagraphs 3-401.11(A)(1) or (2); or
- (B) Included in ¶ 3-401.11(D).

3-302.14 Protection from Unapproved Additives.*

- (A) FOOD shall be protected from contamination that may result from the addition of, as specified in § 3-202.12:
  - (1) Unsafe or unAPPROVED FOOD or COLOR ADDITIVES; and
  - (2) Unsafe or unAPPROVED levels of APPROVED FOOD and COLOR ADDITIVES.
- (B) A FOOD EMPLOYEE may not:

- (1) Apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or to a FOOD considered to be a good source of vitamin B_1; or

- (2) Serve or sell FOOD specified under Subparagraph (B)(1) of this section that is treated with sulfiting agents before receipt by the FOOD ESTABLISHMENT, *except that grapes need not meet this subparagraph*.

3-304.15 Gloves, Use Limitation.

- (A) If used, SINGLE-USE gloves shall be used for only one task such as working with READY-TO-EAT FOOD or with raw animal FOOD, used for no other purpose, and discarded when damaged or soiled, or when interruptions occur in the operation.

- (B) Except as specified in ¶ (C) of this section, slash-resistant gloves that are used to protect the hands during operations requiring cutting shall be used in direct contact only with FOOD that is subsequently cooked as specified under Part 3-4 such as frozen FOOD or a PRIMAL CUT of MEAT.

- (C) *Slash-resistant gloves may be used with* READY-TO-EAT FOOD *that will not be subsequently cooked if the slash-resistant gloves have a* SMOOTH*, durable, and nonabsorbent outer surface; or if the slash-resistant gloves are covered with a* SMOOTH*, durable, nonabsorbent glove, or a* SINGLE-USE *glove*.

- (D) Cloth gloves may not be used in direct contact with FOOD *unless the* FOOD *is subsequently cooked as required under Part 3-4 such as frozen* FOOD *or a* PRIMAL CUT *of* MEAT.

"Single-service articles" means tableware, carry-out utensils, and other items such as bags, containers, placemats, stirrers, straws, toothpicks, and wrappers that are designed and constructed for one time, one person **use**.

(78) **Single-Use Articles.**

(a) **"Single-use articles"** means utensils and bulk food containers designed and constructed to be used once and discarded.

(b) **"Single-use articles"** includes items such as wax paper, butcher paper, plastic wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, and number 10 cans which do not meet the materials, durability, strength, and cleanability specifications under §§ 4-101.11, 4-201.11, and 4-202.11 for multiuse utensils.

(87) **"Utensil"** means a food-contact implement or container used in the storage, preparation, transportation, dispensing, sale, or service of food, such as kitchenware or

tableware that is multiuse, **single**-service, or **single**-**use**; **gloves** used in contact with food; and food temperature measuring devices.
89) "Utensil" means a FOOD-contact implement or container used in the storage, preparation, transportation, dispensing, sale, or service of FOOD, such as KITCHENWARE or TABLEWARE that is multiuse, ***SINGLE***-SERVICE, or ***SINGLE-USE***; ***gloves*** used in contact with FOOD; FOOD TEMPERATURE MEASURING DEVICES; and probe-type price or identification tags used in contact with FOOD.

1. **HANDLING OF CONTAINERS AND EQUIPMENT**

   Handling of fabricated containers, and container and closure-contact surfaces shall be kept to a minimum. Handlers shall sanitize their hands frequently or wear clean, **single**-**use** **gloves**.

Spontaneous Combustion of Latex Gloves

Key words: **latex** **gloves**, spontaneous combustion, additives, forensics

During 1994 and 1995, four warehouse fires were reported as having been caused by the spontaneous combustion of **latex** examination **gloves** stored therein. FDA was alerted to

the problem and an investigation was initiated. **Latex** does not ordinarily give rise to spontaneous combustion, so the suspect **gloves** were tested for excess generation of heat. The suspect **gloves**, which were powder-free **latex** examination **gloves** labeled as having been made in China and control powder-free **latex** examination **gloves**, were taken through identical heating profiles while the internal temperature of the glove mass was monitored.

A clear overheating by the suspect **gloves** indicated a potential for spontaneous combustion. Infrared studies of both the surfaces (using attenuated total reflection FTIR) of the **gloves** as well as extracts (using transmission FTIR) from the **gloves** showed a difference in the chemical makeup of the suspect **gloves** from control **gloves**. It was concluded that the **gloves** were improperly manufactured using additives to the **latex** that were inappropriate and unsafe. A public health advisory was issued concerning the storage of suspect **gloves**.

INFECTION CONTROL

Environmental Degradation of Latex Gloves: the Effects of Elevated Temperature on Tensile Strength

Key words: **latex gloves**, environmental degradation, tensile test, chlorination, standards, forensics

Latex gloves are widely used as a primary barrier to the spread of disease in various situations, including direct medical care, surgery, and emergency care. A Federal-State contract study in the State of Washington recently evaluated the environmental degradation of **latex** condoms and determined that some formulations of condoms are susceptible to significant deterioration due to heat-accelerated and room-temperature aging. Condoms and **gloves** are manufactured in a similar, but not identical manner. The purpose of this study was to evaluate the deterioration of **latex gloves** to determine if the mechanisms identified as important in the environmental degradation of condoms are relevant to **gloves**. This study focuses on whether differences in **latex** glove formulations are important factors in the resistance of the product to high-temperature deterioration, as might occur during shipment or shelf life storage in non-air-conditioned environments.

Sixteen **latex** glove styles were exposed to severely elevated temperature and low humidity (70°C, <15% RH) for periods of 7, 14, and 21 days. These conditions were selected to represent the most severe conditions that may be encountered during shipment and storage. The 16 styles represented various formulations of **latex gloves** (surgeons and examination, powdered and powder-free), manufactured from several sources in six different countries. Traditional tensile testing (ASTM D412) of the exposed **gloves** plus controls (0 days of exposure) was performed.

OST data were evaluated with respect to the effect of heat aging (70°C) on glove degradation over time, as well as the comparative effects of heat aging on different types of **gloves** (powdered vs. powder-free, examination vs. surgeons, and smooth vs. textured). The most notable difference was found between powdered and powder-free **gloves**. The powdered **gloves**, without exception, exhibited a moderate or no statistical decrease in tensile strength over 21 days of exposure. Four of the nine powdered glove styles showed no statistical degradation over time. The tensile strength of the other five types decreased a moderate 10% to 25%. The bulk of this degradation, depending on brand, occurred at various points throughout the 21-day exposure period.

In contrast, of the seven brands of powder-free **gloves**, the tensile strength of five brands significantly decreased (within only 7 days for four brands), followed by a more moderate rate of deterioration. The stress vs. time curves were generally quadratic in nature and the total deterioration in tensile strength ranged from 70% to over 90%. Two powder-free styles did not follow this pattern, but rather followed the more moderate linear degradation pattern characteristic of the powdered **gloves**, exhibiting total decreases in tensile strength of 15% and 25%. One of these two brands was found to be non-chlorinated. The powder removal process of the other brand is currently under investigation. Thus, these results suggest that the chlorination process, which is one of the

most common processes used to render **gloves** free from surface powders, may have detrimental effects on the barrier ability of natural rubber **latex**.

Two direct comparisons could be made on the other glove characteristics mentioned above (texture and use) based on the assumptions that two glove types from the same manufacturer and country were made at the same site in that country and used identical processes and formulations. (These assumptions may be difficult, if not impossible to verify.) Under these assumptions, smooth vs. textured **gloves** (powdered, examination, made in Thailand) were compared using a two-way analysis of variance (ANOVA). It was found that, although neither degraded significantly over time, the smooth **gloves** had significantly ($p<0.0001$) greater tensile strength (approximately 50%) than the textured **gloves**. It is not clear if lower tensile strength is a characteristic of textured **gloves** in general or is peculiar to this pair. A comparison of surgeons vs. examination **gloves** (smooth, powdered, made in the United States) showed no significant difference in tensile strength.

FDA currently accepts the performance limits for **gloves** (new and environmentally aged) specified in ASTM D3577 and D3578. If it is determined that certain formulations of **latex gloves** are more susceptible to environmental degradation than others, and that the ASTM performance limits are inappropriate to assure adequate performance, FDA may need to impose additional requirements on the labeling for handling of **gloves** during shipment or strengthen the requirements for testing to assure adequate performance.

FDA Public Health Advisory: Potential Risk of Spontaneous Combustion in Large Quantities of Patient Examination Gloves (June 27, 1996)

(We encourage you to copy and distribute this Advisory)

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FDA Public Health Advisory:
Potential Risk of Spontaneous Combustion
in Large Quantities of Patient Examination *ORYHV

June 27, 1996

To:  Hospital Administrators            /DWH[ Glove Manufacturers
Hospital Risk Managers             Distributors/Importers
Hospital Procurement Managers

In the spring and summer of 1995, the spontaneous combustion of powder-
free ODWH[
patient
examination JORYHV caused four fires in different states.  The fires
all
occurred in warehouses
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and involved large quantities of non-sterile, powder-free, chlorinated ODWH[JORYHV stored on pallets. All of the JORYHV were labeled "Made in China" and manufacturers' serial numbers indicate they were manufactured between 1992 and 1994. We are concerned about the potential for future fires involving powder-free ODWH[patient examination JORYHV and about glove quality. This Advisory offers recommendations which we believe will help reduce risks.

Investigations by the Food and Drug Administration (FDA), the Bureau of Alcohol, Tobacco, and Firearms (BATF), and local fire departments have identified the fires as having started within JORYHV stored in stacks on pallets. Having ruled out arson, investigators concluded the cause of the fires was spontaneous combustion of the JORYHV. High warehouse temperatures apparently accelerated an exothermic chemical reaction on the chlorinated JORYHV to the point where the ODWH[ignited. This conclusion has been supported by current FDA research and raises continued concern as another hot season arrives. We are also concerned that heating short of ignition temperatures may cause the glove ODWH[to deteriorate and lose its effectiveness as a barrier. (Note that labeling on glove boxes instructs that JORYHV should be stored in a cool and dry place.)

Although our investigation is not complete and research continues, we have identified several factors that may increase the potential risk for fires. The most important of these are the storage environment temperature and mass of the JORYHV. Therefore, do not store large quantities of powder-free ODWH[patient examination JORYHV in conditions of extreme heat. Because all the known fires occurred in a quantity of at least one pallet in warehouses without temperature controls, we consider a large quantity of powder-free ODWH[JORYHV to be one pallet or more stored in a warm to hot location. While it is not possible to identify a maximum safe storage temperature, research has confirmed that the greater the mass quantity of JORYHV, the cooler the temperature must be to avoid fires. The FDA recommends the following precautions:

Avoid a large inventory of powder-free ODWH[JORYHV.

Remove shrink-wrap from pallets of stacked cartons.

Break the stacked cartons on each pallet apart and restack or reconfigure cartons to
facilitate cooling ventilation.
Periodically check powder-free **ODWH[JORYHV**
for characteristics suggesting
deterioration, such as brittleness, tackiness, or an acrid chemical odor or stench.
Rotate your powder-free **ODWH[** glove stock using "first-in-first-out" practices.

If **JORYHV** exhibit any characteristic suggesting deterioration, they should
not be used; it is
doubtful they provide an adequate protective barrier. Should these characteristics be noted, or if
evidence of combustion is observed:
(1) immediately break apart the stacks to dissipate heat,
(2) identify **JORYHV** as hazardous and quarantine or remove,
(3) contact your District FDA office or call FDA Emergency Operations at (301)443-1240, and
(4) contact your local Health Department or local environmental agency regarding the proper
disposition of hazardous materials.

FDA will continue to inspect glove manufacturers and distributors, and to work closely with U.S.
Customs, to help ensure the quality of **ODWH[JORYHV**
in this country. As we learn more we will
provide you with updates via CDRH Facts on Demand, which can be reached by calling
1(800)899-0381 or by accessing the FDA/CDRH Homepage on the Worldwide Web at
http://www.fda.gov/cdrh/cdrhhome and look in New Items.

We are interested in any observations you or your employees may have regarding the quality of
patient examination or surgeons' **JORYHV** that you distribute or purchase.
We encourage you and
your staff to use MedWatch, FDA's voluntary reporting program. Submit these reports to
MedWatch by phone at (800)FDA-1088, by FAX at (800)FDA-1078, or mail to:

MedWatch
Food and Drug Administration
HF-2
5600 Fishers Lane
Rockville, Maryland 20857.

If you have questions about this Public Health Advisory, please contact the Issues Management
Staff, Office of Surveillance and Biometrics, Center for Devices and Radiological Health,
Food and Drug Administration, HFZ-510, 1350 Piccard Drive, Rockville, Maryland, 20850,
by FAX at 240-276-3356, or by e-mail at phann@cdrh.fda.gov.
Additionally, a voice mail

message may be left at 240-276-3357 and your
call will be returned as soon as possible.

Sincerely yours,

D. Bruce Burlington, M.D.
Director
Center for Devices and Radiological Health

Adverse Event Report

UNK LATEX POWDERED/NON POWDERED SURGEONS GLOVES

back to search results

Event Description

Problem: some people are allergic to the natural proteins or the chemical additives found in **latex** med **gloves**, resulting in a wide range of allergic reactions varying from contact dermatitis to anaphylactic shock. The use of powdered **latex gloves** can increase the risk or exacerbate the effects of an allergic reaction, particularly if glove powder comes into contact with the mucous membranes of a sensitized individual. This presents a risk to both pts and hlth care staff. Action: users of **latex gloves** should be made aware of the guidance previously issued by mda: sensitization in the hlth care setting (use of **latex gloves**). In order to reduce the risk of allergic reactions, managers should ensure that: local policies are in place which address the purchase and use of med **gloves**. Local policies address the circumstances under which powdered **gloves** may be used and provide a justification for their continued use, especially in areas of high usage or increased risk such as operating theatres. Individuals who are sensitized to **latex** stop using **latex** med **gloves** and are provided with **gloves** made from an alternative material. These individuals should also avoid work areas where **latex** glove powder particles are likely to be airborne. Purchasers are advised to procure **gloves** taking into consideration the level of extractable **latex** protein content (the device bulletin gives further guidance). Info is available from supplies depts, the supplies authority and med glove mfrs. This safety notice should be brought to the attention of those responsible for med glove policy, purchase and use, and all hlth and social care professionals who use **latex gloves** in the course of their work. Background: in 1996 mda published a device bulletin entitled **latex** sensitization in the hlth care setting (use of **latex gloves**). The bulletin highlighted many of the problems surrounding **latex** allergy, offering guidance and recommending that all hlth care establishments implement local policies to address appropriate glove use and management of staff and pts with known or suspected **latex** allergy. **Latex** is recognized as a sensitizer or substance hazardous to hlth, as defined by the control of substances hazardous to hlth regulations (coshh 1994). Therefore employers have a legal obligation

to comply with the regulations and ensure the safety of employees. As the use of **latex** devices has increased, many countries now recognize and report **latex** allergy as a growing problem, particularly in the hlth care setting. The natural proteins found in **latex** or certain chemical additives used in the mfg process, can act as irritants or allergens for sensitized individuals. This can lead to a variety of allergic reactions, ranging from localized or systemic skin conditions to life-threatening anaphylactic shock.

Catalog Number 5274

Event Date 02/01/1997

Event Type Other **Patient Outcome** Other;

Event Description

One person in the office is experiencing a rash on their hands while wearing **latex gloves**. Reporter states this irritation is occurring with co's **latex gloves** as well as with other brands of **latex gloves**. No medical intervention required. (the customer called to request literature and samples of co's non-**latex gloves**.).

Manufacturer Narrative

Date sent to fda: 8/29/97. B4 and g4 dates are the dates that johnson & johnson medical, incorporated was notified of this complaint. H6 "na" was used due to no lot number and no samples provided. Disclaimer johnson & johnson medical inc. Is submitting this report of an undefined reaction associated with the use of **latex gloves**, not with standing co's belief that the enclosed report, based upon currently available information, does not fall within the applicable regulatory requrements for medical device reporting under 21 cfr part 803. J&j medical is reporting this event becaused an undefined reaction may be a symptom of an immunologically mediated allergy which could, in rare instances, reasonably fit within the reporting requirements if exposure to the allergen were to recur.