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KEYSTONE®
ADJUSTABLE CAP COMPANY, INC.

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February 27, 2014

Nelson-Jameson
2400 East 5th Street
Marshfield, WI 54449
Attention: Carol Blakey and Brianna Nikolai

Re: Lab Coats – LC0-WE-NW and LC0-RE-NW

Dear Carol and Brianna,

Please be advised that all of Keystone's disposable protective garments produced from polypropylene, polyethylene, or nylon comply with **The Code of Federal Regulations – Title 21** – Food and Drugs, Chapter 1 – Food and Drug Administration, Department of Health and Human Services, Subchapter B – Food For human Consumption, Part 177 INDIRECT FOOD ADDITIVES: POLYMERS.

The Code of Federal Regulations (CFR) is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. Title 21 of the CFR is reserved for rules of the Food and Drug Administration.

Please see Subpart B – Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces – Sections 177.1520, 177.1600, 177.1500, 177, which specifically pertains to products.

If I can be of further assistance, please do not hesitate to contact me.

Sincerely,

Andrew Feinstein
CEO
Keystone Cap Company, Inc.

Code of Federal Regulations - Title 21 - Food and Drugs

The Code of Federal Regulations (CFR) is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government.. Title 21 of the CFR is reserved for rules of the Food and Drug Administration. Each title (or volume) of the CFR is revised once each calendar year. A revised Title 21 is issued on approximately April 1st of each year and is usually available here several months later.

CFR 21 was downloaded from the files of the Government Printing Office (GPO) and contains the most recent revision. The CFR at GPO, both current and historical, can also be searched directly at: http://www.gpoaccess.gov/cfr/index.html[1].

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION (CONTINUED)

PART 177 INDIRECT FOOD ADDITIVES: POLYMERS

Subpart A [Reserved]

Subpart B--Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces

§ 177.1010 - Acrylic and modified acrylic plastics, semirigid and rigid.
§ 177.1020 - Acrylonitrile/butadiene/styrene co-polymer.
§ 177.1030 - Acrylonitrile/butadiene/styrene/methyl methacrylate copolymer.
§ 177.1040 - Acrylonitrile/styrene copoly-mer.
§ 177.1050 - Acrylonitrile/styrene copoly-mer modified with butadiene/styrene elastomer.
§ 177.1060 - n-Alkylglutarimide/acrylic copolymers.
§ 177.1200 - Cellophane.
§ 177.1210 - Closures with sealing gaskets for food containers.
§ 177.1211 - Cross-linked polyacrylate copolymers.
§ 177.1240 - 1,4-Cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate copolymer.
§ 177.1310 - Ethylene-acrylic acid copolymers.
§ 177.1312 - Ethylene-carbon monoxide copolymers.
§ 177.1315 - Ethylene-1, 4-cyclohexylene dimethylene terephthalate copolymers.
§ 177.1320 - Ethylene-ethyl acrylate copolymers.
§ 177.1330 - Ionomeric resins.
§ 177.1340 - Ethylene-methyl acrylate copolymer resins.
§ 177.1345 - Ethylene/1,3-phenylene oxyethylene isophthalate/ terephthalate copolymer.
§ 177.1350 - Ethylene-vinyl acetate copolymers.
§ 177.1360 - Ethylene-vinyl acetate-vinyl alcohol copolymers.
§ 177.1380 - Fluorocarbon resins.
§ 177.1390 - Laminate structures for use at temperatures of 250 deg. F and above.
§ 177.1395 - Laminate structures for use at temperatures between 120 deg. F and 250 deg. F.
§ 177.1400 - Hydroxyethyl cellulose film, water-insoluble.
§ 177.1420 - Isobutylene polymers.
§ 177.1430 - Isobutylene-butene copolymers.
§ 177.1440 - 4,4'-Isopropylidenediphenol-epichlorohydrin resins minimum molecular weight 10,000.
§ 177.1460 - Melamine-formaldehyde resins in molded articles.
§ 177.1480 - Nitrile rubber modified acrylonitrile-methyl acrylate copolymers.
§ 177.1500 - Nylon resins.

Subpart C--Substances for Use Only as Components of Articles Intended for Repeated Use

[Code of Federal Regulations]
[Title 21, Volume 3]
[Revised as of April 1, 2010]
[CITE: 21CFR177.1600]

Sec. 177.1600 Polyethylene resins, carboxyl modified.

Carboxyl-modified polyethylene resins may be safely used as the food-contact surface of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) For the purpose of this section, carboxyl-modified polyethylene resins consist of basic polymers produced when ethylene-methyl acrylate basic copolymers, containing no more than 25 weight percent of polymer units derived from methyl acrylate, are made to react in an aqueous medium with one or more of the following substances:

Ammonium hydroxide.

Calcium carbonate.

Potassium hydroxide.

Sodium hydroxide.

(b) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of 176.170(c) of this chapter, yields total extractives in each extracting solvent not to exceed 0.5 milligram per square inch of food-contact surface as determined by the methods described in 176.170(d) of this chapter; and if the finished food-contact article is itself the subject of a regulation in parts 174, 175, 176, 177, 178, and 179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation. In testing the finished food-contact articles, a separate test sample is to be used for each required extracting solvent.

(c) The provisions of paragraph (b) of this section are not applicable to carboxyl-modified polyethylene resins used in food-packaging adhesives complying with 175.105 of this chapter.

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION (CONTINUED)

PART 177 -- INDIRECT FOOD ADDITIVES: POLYMERS

Subpart B--Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces

Sec. 177.1520 Olefin polymers.

The olefin polymers listed in paragraph (a) of this section may be safely used as articles or components of articles intended for use in contact with food, subject to the provisions of this section.

(a) For the purpose of this section, olefin polymers are basic polymers manufactured as described in this paragraph, so as to meet the specifications prescribed in paragraph (c) of this section, when tested by the methods described in paragraph (d) of this section.

(1)(i) Polypropylene consists of basic polymers manufactured by the catalytic polymerization of propylene.

(ii) Propylene homopolymer consists of basic polymers manufactured by the catalytic polymerization of propylene with a metallocene catalyst.

(2)(i) Polyethylene consists of basic polymers manufactured by the catalytic polymerization of ethylene.

(ii) Fumaric acid-grafted polyethylene (CAS Reg. No. 26877-81-6) consists of basic polymers manufactured by the catalytic polymerization of ethylene followed by reaction with fumaric acid in the absence of free radical initiators. Such polymers shall contain grafted fumaric acid at levels not to exceed 2 percent by weight of the finished polymer.

(3) Olefin basic copolymers consist of basic copolymers manufactured by the catalytic copolymerization of:

(i) Two or more of the 1-alkenes having 2 to 8 carbon atoms. Such olefin basic copolymers contain not less than 96 weight-percent of polymer units derived from ethylene and/or propylene, except that:

(*a*)(*1*) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and hexene-1 or ethylene and octene-1 shall contain not less than 90 weight-percent of polymer units derived from ethylene;

(*2*) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and hexene-1 shall contain not less than 80 but not more than 90 weight percent of polymer units derived from ethylene.

(*3*) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and pentene-1 shall contain not less than 90 weight-percent of polymer units derived from ethylene.

(*4*) Olefin basic copolymers manufactured by the catalytic polymerization of ethylene and octene-1 shall contain not less than 50 weight-percent of polymer units derived from ethylene.

(*b*) Olefin basic copolymers manufactured by the catalytic copolymerization of ethylene and 4-methylpentene-1 shall contain not less than 89 weight-percent of polymer units derived from ethylene;

(*c*)(*1*) Olefin basic copolymers manufactured by the catalytic copolymerization of two or more of the monomers ethylene, propylene, butene-1, 2-methylpropene-1, and 2,4,4-trimethylpentene-1 shall contain not less than 85 weight-percent of polymer units derived from ethylene and/or propylene;

(*2*) Olefin basic copolymers manufactured by the catalytic copolymerization of propylene and butene-1 shall contain greater than 15 but not greater than 35 weight percent of polymer units derived from butene-1 with the remainder being propylene.

(*d*) Olefin basic terpolymers manufactured by the catalytic copolymerization of ethylene, hexene-1, and either propylene or butene-1, shall contain not less than 85 weight percent polymer units derived from ethylene.

(*e*) Olefin basic copolymers manufactured by the catalytic polymerization of ethylene and octene-1, or ethylene, octene-1, and either hexene-1, butene-1, propylene, or 4-methylpentene-1 shall contain not less than 80 weight percent of polymer units derived from ethylene.

(ii) 4-Methylpentene-1 and 1-alkenes having from 6 to 18 carbon atoms. Such olefin basic copolymers shall contain not less than 95 molar percent of polymer units derived from 4-methylpentene-1, except that copolymers manufactured with 1-alkenes having from 12 to 18 carbon atoms shall contain not less than 97 molar percent of polymer units derived from 4-methylpentene-1; or

(iii) Ethylene and propylene that may contain as modifiers not more than 5 weight-percent of total polymer units derived by copolymerization with one or more of the following monomers:

5-Ethylidine-2-norbornene.

5-Methylene-2-norbornene.

(iv) Ethylene and propylene that may contain as a modifier not more than 4.5 weight percent of total polymer units derived by copolymerization with 1,4-hexadiene.

(v) Ethylene and butene-1 copolymers (CAS Reg. No. 25087-34-7) that shall contain not less than 80 weight percent of polymer units derived from ethylene.

(vi) Olefin basic copolymers (CAS Reg. No. 61615-63-2) manufactured by the catalytic copolymerization of ethylene and propylene with 1,4-hexadiene, followed by reaction with fumaric acid in the absence of free radical initiators. Such polymers shall contain not more than 4.5 percent of polymer units deriving from 1,4-hexadiene by weight of total polymer prior to reaction with fumaric acid and not more than 2.2 percent of grafted fumaric acid by weight of the finished polymer.

(vii) Ethylene and 2-norbornene (CAS Reg. No. 26007-43-2) copolymers that shall contain not less than 30 and not more than 70 mole percent of polymer units derived from 2-norbornene.

(4) Poly(methylpentene) consists of basic polymers manufactured by the catalytic polymerization of 4-methylpentene-1.

(5) Polyethylene graft copolymers consist of polyethylene complying with item 2.2 of paragraph (c) of this section which subsequently has 3a,4,7,7a-tetrahydromethyl-4,7-methanoisobenzofuran-1,3-dione grafted onto it at a level not to exceed 1.7 percent by weight of the finished copolymer.

(6) Ethylene-maleic anhydride copolymers (CAS Reg. No. 9006-26-2) containing no more than 2 percent by weight of copolymer units derived from maleic anhydride.

(b) The basic olefin polymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such basic olefin polymers. The optional adjuvant substances required in the production of the basic olefin polymers or finished food-contact articles may include substances permitted for such use by applicable regulations in parts 170 through 189 of this chapter, substances generally recognized as safe in food and food packaging, substances used in accordance with a prior sanction or approval, and the following:

Sec. 177.1500 Nylon resins.

The nylon resins listed in paragraph (a) of this section may be safely used to produce articles intended for use in processing, handling, and packaging food, subject to the provisions of this section:

(a) The nylon resins are manufactured as described in this paragraph so as to meet the specifications prescribed in paragraph (b) of this section when tested by the methods described in paragraph (d) of this section.

(1) Nylon 66 resins are manufactured by the condensation of hexamethylene-diamine and adipic acid.

(2) Nylon 610 resins are manufactured by the condensation of hexamethylene-diamine and sebacic acid.

(3) Nylon 66/610 resins are manufactured by the condensation of equal-weight mixtures of

nylon 66 salts and nylon 610 salts.

(4) Nylon 6/66 resins manufactured by the condensation and polymerization of Nylon 66 salts and*epsilon* -caprolactam.

(5) Nylon 11 resins are manufactured by the condensation of 11-aminoundecanoic acid.

(6) Nylon 6 resins are manufactured by the polymerization of*epsilon*- caprolactam.

(7) Nylon 66T resins are manufactured by the condensation of hexamethyl-enediamine, adipic acid, and terephthalic acid such that composition in terms of ingredients is 43.1+/-0.2 weight percent hexamethyl-enediamine, 35.3+/-1.2 weight percent adipic acid, and 21.6+/-1.2 weight percent terephthalic acid.

(8) Nylon 612 resins are manufactured by the condensation of hexamethylenediamine and dodecanedioic acid.

(9) Nylon 12 resins are manufactured by the condensation of*omega*- laurolactam.

(10)(i) Impact modified Nylon MXD-6 resins (CAS Reg. No. 59655-05-9) manufactured by the condensation of adipic acid, 1,3-benzenedimethanamine, and*alpha*- (3-aminopropyl)-*omega*-(3-amino-propoxy)poly- oxyethylene under such conditions that the*alpha* -(3-amino-propyl)-*omega*- (3-aminopropoxy) polyoxyethylene monomer content does not exceed 7 percent by weight of the finished resin.

(ii) Nylon MXD-6 resins (CAS Reg. No. 25718-70-1) manufactured by the condensation of adipic acid and 1,3-benzenedimethanamine.

(11) Nylon 12T resins are manufactured by the condensation of*omega*- laurolactam (CAS Reg. No. 0947-04-6), isophthalic acid (CAS Reg. No. 0121-91-5), and bis(4-amino-3-methylcycl-ohexyl)methane (CAS Reg. No. 6864-37-5) such that the composition in terms of ingredients is 34.4+/-1.5 weight percent*omega* -laurolactam, 26.8+/-0.4 weight percent isophthalic acid, and 38.8+/-0.5 weight percent bis(4-amino-3-methylcyclohexyl)-methane.

(12) Nylon 6I/6T resins (CAS Reg. No. 25750-23-6) are manufactured by the condensation of hexamethylenediamine, terephthalic acid, and isophthalic acid such that 65 to 80 percent of the polymer units are derived from hexamethylene isophthalamide.

(13)(i) Nylon 6/12 resins (CAS Reg. No. 25191-04-2) are manufactured by the copolymerization of a 1 to 1 ratio by weight of*epsilon* -caprolactam and*omega* -laurolactam.

(ii) Nylon 6/12 resins (CAS Reg. No. 25191-04-2) are manufactured by the copolymerization of a ratio of at least 80 weight percent of*epsilon* -caprolactam and no more than 20 weight percent of*omega* -laurolactam.

(14) Nylon 6/69 resins (CAS Reg. No. 51995-62-1) are manufactured by the condensation of 49.5+0.5 weight percent*epsilon* -caprolactam, 19.4+0.2 weight percent hexamethylenediamine and 31.2+0.3 weight percent azelaic acid.

(15) Nylon 46 resins (CAS Reg. No. 50327-77-0) are manufactured by the condensation of 1,4-butanediamine and adipic acid.

(16) Nylon resins PA 6-3-T (CAS Registry No. 26246-77-5) are manufactured by the condensation of 50 mol percent 1,4-benzenedicarboxylic acid, dimethyl ester and 50 mol percent of an equimolar mixture of 2,2,4-trimethyl-1,6-hexanediamine and 2,4,4-trimethyl-1,6-hexanediamine