



The European Union created Regulation (EC) 1935/2004 to provide a common understanding within the EU marketplace regarding the use of certain materials that come in contact with food and the necessary safety measures that must be in place to ensure protection of human health and the best interests of consumers.

The underlying principle is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from the following:

- Being transferred to food in quantities large enough to endanger human health
- Bringing about an unacceptable change in the composition of the food
- Causing deterioration in its sensory properties. (smell, taste, etc.)

The regulation directs that materials must be manufactured in compliance with Good Manufacturing Practices (GMP). ECO2023/2006 (GMP) is a quality assurance certification that provides for full traceability in the production of compliant products. EU10/2011 specification covers plastic and rubber. It stipulates approved stimulants, times and temperatures to run the migration testing and the use of approved rubber chemical ingredients

Users intending to export products for food contact into Europe, are required to use materials that have been tested and deemed EC1935/2004 compliant. This standard is a much more stringent specification when compared to FDA compliance.

In the United States, compounds formulated with the materials listed under the FDA Code of Federal Regulations, Title 21, Part 177.2600 are generally considered acceptable for food contact applications. Compliance with the code is self regulated meaning that the compounder certifies the material was made with the approved ingredients. The FDA does not test or specifically approve rubber compounds.

3-A sanitary standards were introduced for the hygienic design of equipment used in the dairy industry to promote food safety. The 3-A Sanitary Standards are an independent not-for-profit corporation made up of four associations: American Dairy Products Institute, International Dairy Foods Association, Food Processing Suppliers Association and International Association for Food Protection. Standard 18-03 Multiple Use Rubber and Rubber-Like materials applies to the products manufactured by PAI.

Precision Associates has 4 compounds that are EC1935/2004 approved :

Compound	Polymer	Duro	Color	Other
8748	FKM	70±5	Black	
19741	SIL	70±5	Salmon	FDA/3A
19748	SIL	70±5	Salmon	FDA/3A
623717	EPDM	70±5	Cream	FDA





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Ask us about our complete line of product literature:

- *Standard O-Rings*
- *Special Size O-Rings*
- *U-Cups*
- *V-Rings*
- *Rod Wipers*
- *X-Rings*
- *8-Rings™*
- *Multiseal® Low Friction Seals*
- *Kurv-Bak™ Hard Rubber Backup Rings*
- *Rubber Balls*
- *Tri-Clamp Sanitary Gaskets*
- *Medical Seals*
- *Custom Molded Seals and Components*

After many years in the rubber business, we've learned to be flexible. We'll bend over backwards to develop custom solutions that meet your needs *precisely*. PAI is the company you can trust for rubber seal solutions **YOUR WAY!**

- **Over 1,000 different compounds**
- **More than 2,700 O-Ring Sizes**
- **On-Site Mold Shop**
- **Custom Molding**
- **99% on-time delivery**
- **ISO 14644-1 Class 7 Clean Room**

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