

FDA, USDA, NSF 51, USP Approved Compounds

The Food and Drug Administration (FDA) has established a list of rubber compounding ingredients which tests have indicated are neither toxic nor carcinogenic. Rubber compounds produced entirely from those ingredients and which also pass the FDA extraction tests are said to "meet the FDA requirements." The FDA does not approve rubber compounds. It is the responsibility of the manufacturer to compound food grade materials from the FDA list of ingredients and establish whether they pass the necessary extraction requirements.

Similar standards are established by the United States Department of Agriculture (USDA).

Additional requirements have been imposed upon seal manufacturers regarding food and beverage service. Parker has developed several materials that are certified to NSF 51, Food and Beverage Standard. In critical medical applications, seals often must be made from an even "cleaner" list of ingredients. The U.S. Pharmacopoeia (USP) Class VI outlines requirements for system toxicity and intracutaneous toxicity for these "cleaner" compounds. The USP Class VI compounds must be made from ingredients with clear histories of biocompatibility that meet tighter requirements for leachates.

Typical applications for our FDA, NSF 51, USDA materials are disposable medical devices, surgical instruments and medical fluid dispensing components, as well as a wide variety of food and beverage handling equipment. The type of approval/certification required generally rests with the end customer's regulatory expectations for the specific application.

| PARKER COMPOUND | POLYMER | HARDNESS | COLOR | SERVICE |
|------------------|---------|----------|-------|---------------------------|
| E1583-70 (63017) | EPDM | 70 | Black | NSF 51 |
| E1549-70 (63447) | EPDM | 70 | Black | NSF 51 |
| EJ150-75 (3077) | EPDM | 75 | Black | FDA, USP Class VI |
| E3609-70 | EPDM | 70 | Black | NSF 51, FDA, USP Class VI |
| E1028-70 | EPDM | 70 | Black | FDA |
| V0680-70 | FKM | 70 | Red | NSF 51, FDA, USDA |
| NJ253-70 (7077) | NBR | 70 | Black | FDA |
| N1219-60 | NBR | 60 | Black | NSF 51, FDA |
| N1220-70 | NBR | 70 | Black | NSF 51, FDA |
| N1069-70 | NBR | 70 | Black | FDA |
| N0508-75 | NBR | 75 | Black | FDA, USDA |
| V8545-75 | FFKM | 75 | Black | FDA |
| V8562-75 | FFKM | 75 | White | FDA |
| S0802-40 | VMQ | 40 | White | FDA |
| S0317-60 | VMQ | 60 | Rust | FDA, USDA |
| S1138-70 | VMQ | 70 | Rust | FDA |
| SM150-40 (11354) | VMQ | 40 | Rust | FDA |
| SM151-50 (11355) | VMQ | 50 | Rust | FDA |
| SM152-60 (11356) | VMQ | 60 | Rust | FDA |
| SM153-70 (11357) | VMQ | 70 | Rust | FDA |
| S0355-75 | VMQ | 75 | Rust | FDA, USDA |

NSF 61 Approved Compounds

NSF 61 - Drinking Water System Components - is the nationally recognized health effects standard for all devices, components and materials which contact drinking water. Parker's O-Ring Division has developed several materials that are certified to NSF 61. Many of these materials are approved for use in the United Kingdom (WRAS), and Germany (KTW) as well as North America.

NSF International - is an industry regulating agency that was established in 1944. Recognized by ANSI (American National Standards Institute), NSF maintains qualification standards and criteria for a wide range of products, including potable water components and delivery systems.

| PARKER COMPOUND | POLYMER | HARD-NESS | WATER CONTACT TEMP | SERVICE |
|------------------|---------|-----------|--------------------|---------------------------------------------------------------------------------------------|
| E1583-70 (63017) | EPDM | 70 | Commercial Hot ** | NSF 61 Internally lubricated, ideal for high volume applications |
| E1561-60 (63446) | EPDM | 60 | Commercial Hot ** | NSF 61, WRAS, KTW, ideal for high volume applications |
| E1549-70 (63447) | EPDM | 70 | Commercial Hot ** | NSF 61, WRAS, KTW, excellent compression set resistance, ideal for high volume applications |
| E1570-70 | EPDM | 70 | Commercial Hot ** | NSF 61 Internally lubricated |
| E1571-70 | EPDM | 70 | Commercial Hot ** | NSF 61 |
| E1244-70 | EPDM | 70 | Commercial Hot ** | NSF 61 Internally lubricated |
| E1257-70 | EPDM | 70 | Commercial Hot ** | NSF 61 Chloramine Resistant |
| E3609-70 | EPDM | 70 | Commercial Hot ** | NSF 61, WRAS, KTW, excellent compression set resistance |
| EJ151-80 (3958) | EPDM | 80 | Commercial Hot ** | NSF 61, WRAS, KTW |
| N1517-70 | Nitrile | 70 | Commercial Hot ** | NSF 61 |
| N1510-70 (67997) | Nitrile | 70 | Commercial Hot ** | NSF 61 |
| N0757-70 | Nitrile | 70 | Cold Water*** | NSF 61 |

* NSF 61 listed materials given a commercial hot water rating are also certified for cold water

** Commercial Hot = Tested at 82° C (180° F) (Commercial Hot)

*** Cold Water = Tested at 23° C (73.4° F)