







## **VULCAN MECHANICAL SEALS**

# F.D.A. AND E.C. FOOD INDUSTRY REGULATIONS COMPLIANCE



## F.D.A. AND E.C. FOOD INDUSTRY COMPLIANCE



#### INTRODUCTION

Vulcan now offer from stock all common food and dairy seals, specified and specifically manufactured to be complaint with F.D.A. and E.C. Food Industry Regulations.

The principle underlying European Community (E.C) Regulation Number 1935/2004 "On Materials and Articles Intended to Come into Contact with Food" is that any material or article intended to come into contact directly or indirectly with food, must be sufficiently inert to preclude substances from being transferred to food, in quantities large enough to endanger human health, or to bring about an unacceptable change in the composition of the food, or a deterioration in its organoleptic properties".

Understanding the implications of these regulations is increasingly leading to food industry manufacturers stipulating that all materials, including mechanical seals, that come into contact with food should be made from F.D.A. compliant materials, which comply with the above E.C. Regulations and have full traceability of said materials.

In order to comply with these regulations where specified and as an integral part of Vulcan's standard policy to only offer superior designs and materials, we have made available from stock, all of our market leading range of food industry seals, specified to be manufactured from certified compliant materials to meet U.S. and European Food Industry Regulations.

The materials, production and surface finish of Vulcan's Food Industry Compliant Seals have been carefully specified to meet all of the EHEDG recommendations and criteria. Full details are available in the materials guideline section of this information pack.

This range of Vulcan seals offer superior performance, reliability and life. They are specified to be compliant to the existing known regulations applicable in Europe and North America.

Vulcan Disclaimer - Advice



## F.D.A. AND E.C. FOOD INDUSTRY COMPLIANCE



#### **MATERIAL GUIDELINES**

These materials are specified to comply firstly with Part 177 of Title 21 of the Food and Drug Administration Regulations for safe use as articles or components of articles for producing, manufacturing, processing, preparing, treating, packing, transporting or holding food, in accordance with FDA Regulation 21. CFR.177.1550. and 177.2600.

Secondly, The Sub Group Mechanical Seals of the European Hygienic Engineering & Design Group (EHEDG), Specification of August 2002, stipulates requirements for component materials of mechanical seals, which come into contact with food.

## Section 4.3.1.1. Carbon-Graphite

EHEDG Specification: "Carbon/Graphite materials must meet FDA –Regulations (CFR 21). Typical values for the open porosity of these materials should be less than 0.5%. Pore size within the material are in the range of 2 -55µm and Ra value maximum 0.8."

Vulcan Specification: M825 grade of Carbon, with approval certification available from Vulcan's selected Carbon manufacturer. This carbon grade is resin impregnated both prior to and subsequent to machining to minimise porosity.

### Section 4.3.1.2. Ceramics and Silicon Carbide

EHEDG Specification: "Both Aluminium Oxide (Al<sup>2</sup>O<sup>3</sup>) Ceramic and Silicon Carbide (SiC) are made by sintering pressed powder. Porosity occurs at the junction of grains. The apparent porosity of sintered silicon carbide is less than 0.25%. The pore-size is less than 20µm, and Ra values of the surfaces are typically less than 0.8µm. Care must be taken that pure SiC is used, because any free silicon is easily affected by product or cleaning agents. The apparent porosity of aluminium oxide is likely to be less than 0.5%, with a pore size less than 30µm. Typical sintered surface finishes are less then 0.8µm Ra."

Vulcan Specification: Silicon Carbide Faces are considered to be G.R.A.S. (Generally Regarded As Safe). We solely specify our pure sintered Silicon Carbide, CNC ground on all surfaces. Reaction Bonded SiC is not utilised, as the free Silicon is readily attacked by the Caustics in C.I.P. Systems. Vulcan's Ceramic Grade is 99.5% pure, providing better integrity and performance, than the 95/96% pure Ceramics utilised as standard elsewhere.

Vulcan Disclaimer - Advice



## F.D.A. AND E.C. FOOD INDUSTRY COMPLIANCE



### Section 4.3.1.3 Hard Metal

EHEDG Specification: "Tungsten Carbide particles are held together by a binder material. Chemical resistant binder materials such as nickel should be used in food applications. Any resin impregnants used shall be produced from monomers according to the Plastic Directive (90/128/EEC), which in addition are also approved by the FDA. Metal impregnants such as antimony or babbit are not permitted! Machining procedures are to ensure good surface properties".

Vulcan Specification: Nickel Bound T.C. which is CNC ground on all surfaces to comply.

### Section 4.3.2. Elastomer Materials

EHEDG Specification: "The material should be selected according to the requirements of the responsible certified bodies such as FDA and BGVV or evolving European Legislation. The materials shall be smooth and free of flash lines, of low porosity, without blisters and tears at any surface in contact with the produce-wetted area".

Vulcan Specification: Our Elastomer Components and 'O' Rings are moulded from FDA Compliant Material Compounds and manufactured in accordance with Title 21. Code of Federal Regulations – paragraph 177.2600. and 177.1550.

### Section 4.3.3. Metal Materials

EHEDG Specification: "The metal components shall be made of austenitic stainless steel to a specification corresponding to AISI type 316 or EN 10088 Part 1. Springs must be made of corrosion resistant materials. The metal surface finishes should be 0.8 µm Ra or better at the product side".

Vulcan Specification: All our metal parts and springs are specified compliant AlSI Type 316 austenite stainless steel (as specified by EHEDG)and are manufactured on our GILDEMEISTER machining centres to produce seal part surface finishes of within 0.8 Ra  $\mu$ m. This standard is required to inhibit microbacterial growth on seal surfaces.

Vulcan Disclaimer - Advice



## F.D.A. AND E.C. FOOD INDUSTRY COMPLIANCE



### **PURCHASING VULCAN COMPLAINT MECHNICAL SEALS**

#### **Product Codes**

In order to specify or purchase these seals, merely add the prefix Y - to the existing stock code (replacing the W – prefix if you are already specifying the same).

## Food Industry Seals - Vulcan Brochure Section 11b

Vulcan have made available from stock, all of our industry leading range of food industry seals, specified to be manufactured from certified compliant materials to meet U.S. and European Food Industry Regulations.

Please contact the Vulcan Internal Sales office for the up to date pricing and stock availability.

### Non Food Industry Specific Mechanical Seals

Vulcan are pleased to offer all of our industry leading range mechanical seals manufactured from certified compliant materials to meet U.S. and European Food Industry Regulations. These are not commonly available ex-stock from Vulcan but can be provided against minimum production quantity orders. Vulcan will also look at all opportunities to provide bespoke mechanical seals in complaint materials.

Please contact the Vulcan Technical office for a quotation.

#### Certification

We can provide Vulcan's Certificates of Compliance for specific product orders, to the above Vulcan Specifications, upon request.

Vulcan Disclaimer - Advice