

Huhnseal Declaration of Compliance for Hygienic Applications

The Mechanical Seal Manufacturer **Huhnseal AB** hereby declares that when specified and with the intended use in Hygienic Applications for all types of food and/or pharmaceuticals, the Seals supplied and the components that they contain are in conformity with the requirements of:

- Regulation **(EC) No 1935 / 2004** - "on materials and articles intended to come into contact with food"
 - U.S. Food & Drug Administration (**FDA**)*
 - **3-A®** Sanitary Standards, Inc.*
 - United States Pharmacopeia (**USP**)*
- Free of Animal Derived Ingredients (**ADI**)
- Regulation **(EC) No 1895/2005** - "on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food"
- Regulation **(EC) No 2023/2006** - "on good manufacturing practice for materials and articles intended to come into contact with food"
- Regulation **(EC) No 1907/2006 - REACH**
- European directive **RoHS 2 2011/65/EU** - "on the restriction of the use of certain hazardous substances in electrical and electronic equipment"
- Regulation **EU No 10-2011** - "on plastic materials and articles intended to come into contact with food"

*depending on material and component specifications shown in this document

Regulation (EC) No 1935/2004
 "on materials and articles intended to come into contact with food"

Traceability

All relevant components are traceable to material documentation for the substances they are made of and have no effect regarding health of human beings or animals. Furthermore, all mechanical seals of cartridge type supplied are clearly and indelibly marked with a unique ID number, which allows for traceability of their components and a follow-up of modifications during repair, upgrades, and history.

Material compliance

Steel Components:

The steel components in contact with the product are commonly manufactured in stainless steel of type EN 1.4404/AISI 316L and/or EN 1.4460/AISI 329. The material fulfils the current specifications with regard to composition and is not contaminated by unwanted components. If the grade of stainless steel is correctly specified for the application, it will not change the specification or quality of the food.

Material certificate of type **3.1**, according to **EN 10204:2004** - "test certificates for stainless steel products", can be supplied upon request.

Seal face Components:

All compounds used are traceable to documentation for the substances they are made of. Depending on material specifications and requirements for certificates, when specified upon order the following certificates are available for the different seal face materials:

Silicon Carbide / Tungsten Carbide	<p>Silicon Carbide and Tungsten Carbide seal faces in contact with the product are acceptable for use as seals in food processing equipment according to the FDA - Generally Recognised As Safe (GRAS).</p> <p>Seal faces in contact with the product have been tested according to EN 1388-1:1995 - "Materials and articles in contact with foodstuffs. Silicate surfaces. Determination of the release of lead and cadmium from ceramic ware" and have been found not to release any lead or cadmium.</p>
Carbon	<p>The carbon rings are compliant to US FDA CFR 21 §177.2410 "Phenolic resins in molded articles".</p>

Diamond coating	<p>Diamond coatings can be applied on a Silicon Carbide or a Tungsten Carbide seal face to reduce the friction. Certain grades are useful in dry running conditions at low speed (<1,5m/s), others are used in wet applications to reduce the heat generation.</p> <p>All coatings used are highly resistant to corrosion and abrasion. When the mechanical seal is running under the conditions of its intended use, there is little or no likelihood of diamond coating migrating into the product. Huhnseal will confirm suitability of the different coating grades when informed about application details.</p>
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Rubber Components:

All compounds used are traceable to documentation for the substances they are made of. This documentation consists of supplier certificates obtained following evaluations done according to:

US FDA CFR 21	U.S. Food and Drug Administration Code of Federal Regulation Title 21 Section §177.2600 - "Rubber articles intended for repeated use"
3-A® Sanitary Standard	3-A® standard Number 18-03 - "Standard for rubber and rubber like materials", following the specification for class II or better
USP Class VI	United States Pharmacopeia Class VI - "plastic classification"

Depending on material specifications and requirements for certificates, when specified upon order the following certificates are available for the different rubber components:

O-rings	Material	FDA	3-A®	USP VI
	HNBR	Yes	Yes	No
EPDM	Yes	Yes	Yes	
FPM	Yes	Yes	Yes	
FFPM	Yes	Yes	Yes	
LIPORINGS®	Material	FDA	3-A®	USP VI
	HNBR	Yes	Yes	No
	EPDM	Yes	Yes	Yes
	FPM	Yes	Yes	Yes
	FFPM	Yes	No	Yes

Encapsulated O-rings

All compounds used are traceable to documentation for the substances they are made of. This documentation consists of supplier certificates obtained following evaluations done according to:

US FDA CFR 21	U.S. Food and Drug Administration Code of Federal Regulation Title 21 Section §177.1550 - "Perfluorocarbon resins"
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3-A® Sanitary Standard	3-A® standard 18-03 Number 20-22 - "Standard for rubber and rubber like materials", following the specification for class II or better
USP Class VI	United States Pharmacopeia Class VI - "plastic classification"

Animal derived Ingredients (ADI) free materials

Huhnseal AB hereby declares that the components within the mechanical seals and the compounds they are made of, have no effect on the health of human beings or animals. These compounds do not contain, and are not derived from, materials of animal origins. They do not contain specific risk material (**SRM**) and are not associated with risk of Transmissible Spongiform Encephalopathies (**TSE**) or Bovine Spongiform Encephalopathy (**BSE**).

Regulation (EC) No 1895/2005

"on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food"

The Compounds does not contain Bisphenols as described in **1895/2005/EEC**.

Regulation (EC) No 2023/2006

"on good manufacturing practice for materials and articles intended to come into contact with food"

Huhnseal AB declares that its manufacturing practices are compliant to Regulation **(EC) No 2023/2006**. Huhnseal AB complies with Articles 5, 6 and 7 of this Regulation by means of its established Quality Assurance and Control System following ISO 9001:2015, awarded by Bureau Veritas Sweden, certificate number SE006581-1.

Regulation (EC) No 1907/2006 - REACH

European directive RoHS (2011/65/EU)

"on the restriction of the use of certain hazardous substances in electrical and electronic equipment"

The mechanical seals and the components they contain are compliant to the requirements of REACH Regulation **(EC) No. 1907/2006** and European directive **RoHS (2011/65/EU)** and addition Directive **2015/863/EU**.

This means that:

1. To the best of our knowledge, none of the substances mentioned in the current REACH candidate list **dated January 16th 2020** are present in either the articles we purchase from our suppliers or the articles which we manufacture ourselves.
2. To the best of our knowledge, none of the substances mentioned in the "candidate list" shown below is present in either the articles we purchase from our suppliers or the articles which we manufacture ourselves.

Hazardous substances	Maximum concentration
Lead (Pb)	0,1%
Cadmium (Cd)	0,01%
Mercury (Hg)	0,1%
Hexavalent Chromium (Cr6+)	0,1%
Poly Brominated Biphenyls (PBB)	0,1%
Poly Brominated Diphenyl ethers (PBDE)	0,1%
Bis(2-ethylhexyl) phthalate (DEHP)	0,1%
Butyl benzyl phthalate (BBP)	0,1%
Dibutyl phthalate (DBP)	0,1%
Diisobutyl phthalate (DIBP)	0,1%

EU No 10-2011

"on plastic materials and articles intended to come into contact with food"

Huhnseal mechanical seals do not contain any parts, intended to come in contact with the product, manufactured from plastic materials. The regulation **EU 10-2011** is therefore not applicable for the mechanical seals.

Landskrona, Sweden
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Susanne Berezin
Product Development Manager
Huhnseal AB