

Declaration of Conformity food contact directives

LESER GmbH & Co.KG confirms the fulfillment of the requirements of the following Regulations. The conformity applies to the Clean Service Safety valves 481, 483, 484, 485, 488 and SVL488 with the listed components, which are intended to come into contact with food.

- EC1935/2004 On materials and articles intended to come into contact with food.
- EC 2023/2006 On good manufacturing practice for materials and articles intended to come into contact with food.
- FDA Code of Federal Regulations - Title 21 – Food and Drugs: Part 177.2600


Food contact materials in line with above listed regulations for series Clean Service.

Table 1 Food contact materials in line with above listed regulations for series Clean Service

Component	Option Code	Standard Material	Material name	EC 1935 – Conformity	FDA – Title 21: Part 177.2600 conformity
O-ring	J22	EPDM	EPDM E7502 EPDM E7581	✓	✓
	J23	FKM	HITEC FKM	✓	✓
	J20	FFKM	FFKM J9515 6230 KALREZ	✓	✓
Body – Inlet Body	standard	Stainless steel	316L / 1.4404	✓	not applicable
			316L / 1.4435-BN2		
Disc	standard	Stainless steel	316L / 1.4404	✓	not applicable

2023-06-21

Date



Director R&D - Dr. Michael Heß



Material Declaration of Compliance		
Material Code:		E7502
Elastomere base <i>Elastomerbasis</i>	DIN ISO 1629	EPDM
Hardness <i>Härte</i>	DIN ISO 7619-1	70 ± 5 Shore A
Colour <i>Farbe</i>		black / schwarz
BAM	<p>Use in valves and fittings or other components for gaseous oxygen services at: <i>Verwendung in Armaturen und anderen Anlageteilen für gasförmigen Sauerstoff bei folgenden Betriebsbedingungen:</i></p> <p style="text-align: center;">max. 60 °C / max. 10 bar</p> <p>The test results refer exclusively to the tested batch of the material. If regular batch tests are required, this must be clarified with the responsible technical contact. <i>Die Prüfergebnisse beziehen sich ausschließlich auf die untersuchte Charge des Werkstoffes. Werden regelmäßige Chargenuntersuchungen benötigt, muss dies mit dem zuständigen technischen Ansprechpartner abgeklärt werden.</i></p>	
3A-Sanitary	<p>complies with the test requirements of / <i>erfüllt die Prüfanforderungen nach</i></p> <p>„3-A® Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18-03“:</p> <p style="text-align: center;">C3.1, C2.1.1, C2.2.2, C2.2.3, D4.6, D4.8, D4.9</p> <p style="text-align: center;">Class I (Sterilization Temperature up to 149°C/300°F)</p> <p>EPDM: low-fat tolerances rubber (max. 8% of milk fat)</p>	

*This is to emphasise that the customer himself is obliged to test the material with regard to its suitability in the application.
Dies befreit den Abnehmer insbesondere nicht davon, selbst die Eignung unserer Ware für den beabsichtigten Verwendungszweck zu prüfen.*

31.01.2020 / GMDB

page/Seite 1 / 3

Trelleborg Sealing Solutions Germany GmbH
Schockenriedstraße 1, 70565 Stuttgart, Tel.: +49 (0)711 7864 0
Geschäftsführer: Carsten Stehle (Vors.), Jennifer Ruffler, Jochen Sanguinette, Dr. Thomas Uhlig
Stz und Registergericht Stuttgart HRB 21275, Tax ID: DE 119553041, www.tss.trelleborg.com/de

Disclosure cat.:	I	proofread by:	Bi	publish date:	06/29/23	effect. date:	06/23
author:	MHe	released by:	Hes	replaces:	LID_DE_	status:	Published
resp. depart.:	M	date of release:	06/29/23	revision No.:	0		
doc. type:	LID	change rep. No.:	NA	retention period:	10y.	prot. class:	public



Material Declaration of Compliance

Material Code:

E7502


FDA	<p>complies with Regulation 21 CFR 177.2600 of the US-American Food and Drug Administration (FDA).</p> <p><i>entspricht der Verordnung 21. CFR 177.2600 der US-amerikanischen Food and Drug Administration (FDA).</i></p>
------------	---

Regulation (EC) 1935/2004 Article 3	<p>passed the migration and sensory requirements of the German Food and Feed Code (LFGB), The Federal Institute for Risk Assessment (BfR) XXI, Category 1, and Article 3 of Regulation (EC) 1935/2004 for aqueous, acidic, alcoholic and fatty food. Test date: 2010-07-30.</p> <p><i>erfüllt die Anforderungen für Globalmigration und Sensorik laut Lebensmittel- und Futtermittelgesetzbuch (LFGB), Bundesinstitut für Risikobewertung (BfR) XXI, Kategorie 1 und Verordnung (EG) 1935/2004 Artikel 3 für wässrige, säure-, alkohol- und fett haltige Lebensmittel. Prüfdatum: 30.07.2010.</i></p>
--	---

USP	Chapter 87	<p>BIOLOGICAL REACTIVITY TESTS; IN VITRO</p> <p>weist keine zytotoxische Wirkung auf gemäß / <i>has no cytotoxic effects in all extracts acc. to DIN EN ISO 10993-5 / USP 26, 2003, Chapter 87.</i></p>
	Chapter 88	<p>BIOLOGICAL REACTIVITY TESTS; IN VIVO</p> <p>erfüllt die Anforderungen der / <i>complies with the requirements of: „Class VI“ (121°C), USP 26, 2003, Chapter 88.</i></p>
	Chapter 381	<p>PHYSICO CHEMICAL TESTS</p> <p>erfüllt die Anforderungen der / <i>complies with the requirements of: USP 34, 2011, Chapter 381.</i></p>

*This is to emphasise that the customer himself is obliged to test the material with regard to its suitability in the application.
Dies befreit den Abnehmer insbesondere nicht davon, selbst die Eignung unserer Ware für den beabsichtigten Verwendungszweck zu prüfen.*



Material Declaration of Compliance	
Material Code: E7502	
UL 94 HB	<p>was tested by Testing Center UL International TTC GmbH according to UL 94 and is conform to flammability rating according to HB for test piece thickness < 3 mm and rate of fire ≤ 75 mm/min. This test result does not include the registration at UL.</p> <p><i>wurde vom Prüfinstitut UL International TTC GmbH nach UL 94 geprüft und entspricht der Brennbarkeitsklasse HB für Probekörperdicke < 3 mm und Brenngeschwindigkeit ≤ 75 mm/min. Das Prüfergebnis beinhaltet keine Listung bei UL.</i></p>
ADI-free	<p>is free of animal derived ingredients (ADI) and do not contain any raw materials derived from bovine or animal sources.</p> <p><i>ist frei von tierischen Bestandteilen, bzw. enthält keine Inhaltsstoffe auf tierischer Basis.</i></p>
	<p>TSS does not recommend using EPDM in edible oils and fats, only in milk products with max.8% of milk fat.</p> <p><i>TSS rät davon ab EPDM in Speiseöle und Speisefette einzusetzen, sondern nur in Milchprodukte mit max. 8% Milchfett.</i></p>

This is to emphasise that the customer himself is obliged to test the material with regard to its suitability in the application.
Dies befreit den Abnehmer insbesondere nicht davon, selbst die Eignung unserer Ware für den beabsichtigten Verwendungszweck zu prüfen.

31.01.2020 / GMDB

page/Seite 3 / 3

Trelleborg Sealing Solutions Germany GmbH
Schockenriedstraße 1, 70565 Stuttgart, Tel.: +49 (0)711 7864 0
Geschäftsführer: Carsten Stehle (Vors.), Jennifer Ruffler, Jochen Sanguinette, Dr. Thomas Uhlig
Sitz und Registergericht Stuttgart HRB 21275, Tax ID: DE 119553041, www.tss.trelleborg.com/de

Disclosure cat.:	I	proofread by:	Bi	publish date:	06/29/23	effect. date:	06/23
author:	MHe	released by:	Hes	replaces:	LID_DE_	status:	Published
resp. depart.:	M	date of release:	06/29/23	revision No.:	0		
doc. type:	LID	change rep. No.:	NA	retention period:	10y.	prot. class:	public



Material Declaration of Compliance	
Material Code:	E7581
Additional Code:	HMFEG
Elastomere base <i>Elastomerbasis</i>	DIN ISO 1629 EPDM
Hardness <i>Härte</i>	DIN ISO 7619-1 70 ± 5 Shore A
Colour <i>Farbe</i>	black / schwarz
Elastomer Guideline Elastomerleitlinie	<p>complies with the requirements of the guideline for hygienic assessment of elastomers in contact with drinking water (cold and hot water) in the product group seals for pipes DN < 80 mm (includes 80mm ≤ DN < 300mm and DN ≥ 300mm)</p> <p><i>entspricht den Anforderungen der Leitlinie zur hygienischen Beurteilung von Elastomeren im Kontakt mit Trinkwasser (Kalt- und Heißwasser) im Bereich Dichtungen für Rohre mit DN < 80 mm (beinhaltet 80mm ≤ DN < 300mm and DN ≥ 300mm).</i></p>
W 270	<p>passed the material requirements acc. to DVGW worksheet W 270 in category D2 of KTW-Empfehlung.</p> <p><i>erfüllt die Werkstoffanforderungen des DVGW-Arbeitsblattes W 270 in der Kategorie D2 der KTW-Empfehlung.</i></p>
WRAS	<p>„WRAS-Approved Product“ British Standard BS6920 Materialindex 5365 approval number / <i>Freigabenummer</i> 1503509 Area of application: Cold- and Hot water up to 85°C <i>Anwendungsbereich: Kalt- und Heißwasser bis 85°C</i></p>
ACS	<p>passed / <i>erfüllt</i>: ACS “French positives lists for drinking water contact”</p>

This is to emphasise that the customer himself is obliged to test the material with regard to its suitability in the application.
Dies befreit den Abnehmer insbesondere nicht davon, selbst die Eignung unserer Ware für den beabsichtigten Verwendungszweck zu prüfen.

05.06.2018 / GMDB

page/Seite 1 / 3



Trelleborg Sealing Solutions Germany GmbH
Handwerkstraße 5-7, 70565 Stuttgart, Tel: +49 (0)711 7864 0, Fax: +49 (0)711 7803 234
Geschäftsführer: Carsten Stehle (Vors.), Jürgen Bosch, Jochen Sanguinette
Sitz und Registergericht Stuttgart HRB 21275, Tax ID: DE 119553041, www.tss.trelleborg.com/de



disclosure cat.:	I	prepared by:	DI	publish date:	06/29/23	effect. date:	06/23
author:	MHe	released by:	Hes	replaces:	LID_DE_	status:	Published
resp. depart.:	M	date of release:	06/29/23	revision No.:	0		
doc. type:	LID	change rep. No.:	NA	retention period:	10y.	prot. class:	public



Material Declaration of Compliance	
Material Code:	E7581
Additional Code:	HMFEG
FDA	<p>complies with Regulation 21 CFR 177.2600 of the US-american Food and Drug Administration (FDA).</p> <p><i>entspricht der Verordnung 21. CFR 177.2600 der US-amerikanischen Food and Drug Administration (FDA).</i></p>
3A-Sanitary	<p>complies with the test requirements of / erfüllt die Prüfanforderungen nach</p> <p>„3-A® Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18-03“:</p> <p style="text-align: center;">C3.1, C2.1.1, C2.2.2, C2.2.3, D4.6, D4.8, D4.9</p> <p style="text-align: center;">Class I (Sterilization Temperature up to 149°C/300°F)</p> <p>EPDM: low-fat tolerances rubber (max. 8% of milk fat)</p>
National Food Safety Standard, China	<p>complies with the standard / erfüllt die Normen</p> <ol style="list-style-type: none"> 1. GB 4806.1-2016 general safety requirements of food contact materials and articles 2. GB 9685-2016 standard for the use of additives for food contact materials 3. GB 31603-2015 General Manufacturing Hygiene Practices for food contact materials and articles 4. GB 4806.11-2016 food contact rubber and articles
ADI-free	<p>is free of animal derived ingredients (ADI) and do not contain any raw materials derived from bovine or animal sources.</p> <p><i>ist frei von tierischen Bestandteilen, bzw. enthält keine Inhaltsstoffe auf tierischer Basis.</i></p>

This is to emphasise that the customer himself is obliged to test the material with regard to its suitability in the application.
Dies befreit den Abnehmer insbesondere nicht davon, selbst die Eignung unserer Ware für den beabsichtigten Verwendungszweck zu prüfen.

05.06.2018 / GMDB

page/Seite 2 / 3



DE AEO F 118278

Trelleborg Sealing Solutions Germany GmbH
 Handwerkerstraße 5-7, 70565 Stuttgart, Tel: +49 (0)711 7864 0, Fax: +49 (0)711 7803 234
 Geschäftsführer: Carsten Stehle (Vors.), Jürgen Bosch, Jochen Sanguinette
 Sitz und Registergericht Stuttgart HRB 21275, Tax ID: DE 119553041, www.tss.trelleborg.com/de



Disclosure cat.:	I	proofread by:	Bi	publish date:	06/29/23	effect. date:	06/23
author:	MHe	released by:	Hes	replaces:	LID_DE_	status:	Published
resp. depart.:	M	date of release:	06/29/23	revision No.:	0		
doc. type:	LID	change rep. No.:	NA	retention period:	10y.	prot. class:	public



Material Declaration of Compliance	
Material Code:	E7581
Additional Code:	HMFEG
Regulation (EC) 1935/2004 Article 3	<p>passed the migration and sensory requirements of the German Food and Feed Code (LFGB), The Federal Institute for Risk Assessment (BfR) XXI, Category 1, and Article 3 of Regulation (EC) 1935/2004 for aqueous, acidic, alcoholic and fatty food. Test date: 2013-08-06. (TSS does not recommend using EPDM in edible oils and fats, only in milk products with max.8% of milk fat)</p> <p><i>erfüllt die Anforderungen für Globalmigration und Sensorik laut Lebensmittel- und Futtermittelgesetzbuch (LFGB), Bundesinstitut für Risikobewertung (BfR) XXI, Kategorie 1 und Verordnung (EG) 1935/2004 Artikel 3 für wässrige, säure-, alkohol- und fetthaltige Lebensmittel. Prüfdatum: 06.08.2013.</i> <i>(TSS rät davon ab EPDM in Speiseöle und Speisefette einzusetzen, sondern nur in Milchprodukte mit max.8% MilCHFett).</i></p>
USP	<p>Chapter 87</p> <p>BIOLOGICAL REACTIVITY TESTS; IN VITRO</p> <p>has no cytotoxic effects in all extracts acc. to / <i>weist keine zytotoxische Wirkung auf gemäß DIN EN ISO 10993-5 / USP 32, 2009, Chapter 87.</i></p>
	<p>Chapter 88</p> <p>BIOLOGICAL REACTIVITY TESTS; IN VIVO</p> <p>complies with the requirements of / <i>erfüllt die Anforderungen der: „Class VI“ (121°C), USP 32, 2009, Chapter 88.</i></p>
BAM	<p>Use in valves and fittings or other components for gaseous oxygen services at:</p> <p><i>Verwendung in Armaturen und anderen Anlageteilen für gasförmigen Sauerstoff bei folgenden Betriebsbedingungen:</i></p> <p style="text-align: center;">max. 60 °C / max. 20 bar</p> <p style="text-align: center;">ignition temperature / Zündtemperatur 172 °C ± 5 °C</p>

This is to emphasise that the customer himself is obliged to test the material with regard to its suitability in the application.
Dies befreit den Abnehmer insbesondere nicht davon, selbst die Eignung unserer Ware für den beabsichtigten Verwendungszweck zu prüfen.

05.06.2018 / GMDB

page/Seite 3 / 3



Trelleborg Sealing Solutions Germany GmbH
Handwerlerstraße 5-7, 70565 Stuttgart, Tel: +49 (0)711 7864 0, Fax: +49 (0)711 7803 234
Geschäftsführer: Carsten Stehle (Vors.), Jürgen Bosch, Jochen Sanguinette
Sitz und Registergericht Stuttgart HRB 21275, Tax ID: DE 119553041, www.tss.trelleborg.com/de



Disclosure cat.:	I	proofread by:	Bi	publish date:	06/29/23	effect. date:	06/23
author:	MHe	released by:	Hes	replaces:	LID_DE_	status:	Published
resp. depart.:	M	date of release:	06/29/23	revision No.:	0		
doc. type:	LID	change rep. No.:	NA	retention period:	10y.	prot. class:	public



Angst+Pfister Group
Group Engineering
Thurgauerstrasse 66
Postfach
CH-8052 Zürich
E-Mail: ch@angst-pfister.com
Internet: www.angst-pfister.com

DECLARATION OF CONFORMITY

in accordance with
DIN EN ISO/IEC 17050

Date: 30 May 2022
Phone: +41 44 306 62 59
Issuer: GAAX

Declaration subject:

Material description:

HITEC® FKM 75.16-04 (FKM 75.5/VA75F)

The material described above meets the requirements stipulated in the following guidelines/standards:

Food & Beverage

- FDA CFR 21 - 177.2600 a) – f)
- EC 1935/2004 (excl. article 15) and EC Regulation 2023/2006 (GMP)
- BfR XXI Category 4 (Migration test BfR XXI Category 2)
- D.M. 21/03/1973 (Migration test)
- Dlgs. 25.01.1992 n.108 Art.2 (ex. DPR 777/82 art 2)- complies with Arsenic content limits
- GB 4806.11-2016 (Migration test)

Expiry date or unlimited

unlimited
unlimited
unlimited
unlimited
unlimited

Medical / Pharma

- USP Class VI, Chapter <87> (In Vitro) and Chapter <88> (In Vivo) - 121°C

Expiry date or unlimited

unlimited

Oil & Gas

- DVGW EN 549 D1/H3
- BAM Tested maximum temperature 150 °C, maximum oxygen pressure 25 bar
- DIN EN 16678 : 2016-02

01 / 2022**
unlimited
unlimited

** periodic inspection tests are running

HITEC® FKM 75.16-04



Other declarations (declaration revision date: July 08, 2021)

The following statement is based on the current state of our knowledge and is valid from the declaration revision date until the document is superseded. The declaration is valid until the Regulations and Directives are amended. Due to possible changes in the underlying Regulations and Directives, it is not guaranteed that the status of this document will remain unchanged. It will be renewed in all cases where the declaration is no longer ensured.

We hereby declare that our compound complies with the Regulations and Directives as below:

- ADI free (free of Animal Derived Ingredients) resp. TSE/BSE related substances
- Latex-free
- BPA, free of Bisphenol A
- PFOA/PFOS free
- Does not contain substance classified as carcinogenic, mutagenic or toxic to reproduction ("CMR") Cat. 1A/1B in accordance with Part 3 of Annex VI to Regulation EC N° 1272/2008 ATP15 to CLP Regulation.
- Endocrine Disruptors (EDs) free

- PAK Cat. 2 (AfPS GS 2019:01)

- REACH (EC) No 1907/2006 and amendments, Annex XIV, Annex XVII and art 59 (SVHC list as of July 08, 2021)
- RoHS 2011/65/EU & 2015/863/EU

- POP Regulation (EU) 2019/1021

- US EPA (United States Environmental Protection Agency), Toxic Substances Control Act (TSCA) section 6(h) resp. decaBDE / PIP 3:1 / 2,4,6-TTBP / HCBP / PCTP.

Angst + Pfister Group Engineering

Zurich, 30 May 2022
(Place and date of issuance)

Valerie Thurau, PhD

Approval and Regulatory Affairs Manager

(Name and signature or equivalent authentication of authorized persons)

A. Gabor

Engineering Data Administrator



Material Declaration of Compliance		
Material Code:	J9515	
Elastomere base <i>Elastomerbasis</i>	DIN ISO 1629	FFKM
Hardness <i>Härte</i>	DIN ISO 7619-1	75 ± 3 Shore A
Colour <i>Farbe</i>		black / schwarz
FDA	<p>complies with Regulation 21 CFR 177.2600 of the US-American Food and Drug Administration (FDA) and meets the extraction requirements according to Regulation 21 CFR 177.2600 (e, f): "Rubber Articles intended for repeated use" and 21 CFR 177.2400 (d)(1): "Perfluorocarbon cured elastomers".</p> <p><i>entspricht der Verordnung 21. CFR 177.2600 der US-amerikanischen Food and Drug Administration (FDA) und erfüllt die geforderten Extraktionsbedingungen gemäß Verordnung 21 CFR 177.2600 (e, f): "Rubber Articles intended for repeated use" und 21 CFR 177.2400 (d)(1): "Perfluorocarbon cured elastomers".</i></p>	
3-A Sanitary	<p>complies with the test requirements of / <i>erfüllt die Prüfanforderungen nach</i></p> <p>„3-A® Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18-03“:</p> <p style="text-align: center;">C3.1, C2.1.1, C2.2.1, C2.2.2, C2.2.3, D4.6, D4.8, D4.9</p> <p style="text-align: center;">Class I (Sterilization Temperature up to 149°C/300°F)</p>	
ADI-free	<p>is free of animal derived ingredients (ADI) and do not contain any raw materials derived from bovine or animal sources.</p> <p><i>ist frei von tierischen Bestandteilen, bzw. enthält keine Inhaltstoffe auf tierischer Basis.</i></p>	

This is to emphasise that the customer himself is obliged to test the material with regard to its suitability in the application.
Dies befreit den Abnehmer insbesondere nicht davon, selbst die Eignung unserer Ware für den beabsichtigten Verwendungszweck zu prüfen.

18.02.2022 / GMDB

page/Seite 1 / 2

Trelleborg Sealing Solutions
www.tss.trelleborg.com

Disclosure cat.:	I	proofread by:	Bi	publish date:	06/29/23	effect. date:	06/23
author:	MHe	released by:	Hes	replaces:	LID_DE_	status:	Published
resp. depart.:	M	date of release:	06/29/23	revision No.:	0		
doc. type:	LID	change rep. No.:	NA	retention period:	10y.	prot. class:	public



Material Declaration of Compliance

Material Code: **J9515**

Regulation (EC) Verordnung (EG) 1935/2004	<p>passed the migration and sensory requirements of the German Food and Feed Code (LFGB), The Federal Institute for Risk Assessment (BfR) XXI, Category 1, and Article 3 of Regulation (EC) 1935/2004 for aqueous, acidic, alcoholic and fatty food. The testing was done according to 82/711/EEC and 85/572/EEC and latest amendments at date of testing (Date: 2010-10-15).</p> <p><i>erfüllt die Anforderungen für Globalmigration und Sensorik laut Lebensmittel- und Futtermittelgesetzbuch (LFGB), Bundesinstitut für Risikobewertung (BfR) XXI, Kategorie 1 und Verordnung (EG) 1935/2004 Artikel 3 für wässrige, saure, alkohol- und fetthaltige Lebensmittel.</i> <i>Die Prüfungen wurden gemäß 82/711/EEC und 85/572/EEC mit den am Prüfdatum geltenden neuesten Ergänzungen durchgeführt (Datum: 15.10.2010).</i></p>
--	--

USP	Chapter 87	<p>BIOLOGICAL REACTIVITY TESTS; IN VITRO</p> <p>has no cytotoxic effects in all extracts acc. to / <i>weist keine zytotoxische Wirkung auf gemäß DIN EN ISO 10993-5 / USP 25, 2002, Chapter 87.</i></p>
	Chapter 88	<p>BIOLOGICAL REACTIVITY TESTS; IN VIVO</p> <p>complies with the requirements of / <i>erfüllt die Anforderungen der: „Class VI“ (121°C), USP 25, 2002, Chapter 88.</i></p>
	Chapter 381	<p>PHYSICO CHEMICAL TESTS</p> <p>erfüllt die Anforderungen der / <i>complies with the requirements of : USP 36, 2013, Chapter 381.</i></p>

This is to emphasise that the customer himself is obliged to test the material with regard to its suitability in the application.
Dies befreit den Abnehmer insbesondere nicht davon, selbst die Eignung unserer Ware für den beabsichtigten Verwendungszweck zu prüfen.

18.02.2022 / GMDB

page/Seite 2 / 2

Trelleborg Sealing Solutions
www.tss.trelleborg.com

Disclosure cat.:	I	proofread by:	Bi	publish date:	06/29/23	effect. date:	06/23
author:	MHe	released by:	Hes	replaces:	LID_DE_	status:	Published
resp. depart.:	M	date of release:	06/29/23	revision No.:	0		
doc. type:	LID	change rep. No.:	NA	retention period:	10y.	prot. class:	public



Kalrez® 6230

PERFLUOROELASTOMER PARTS

DuPont™ Kalrez® 6230 perfluoroelastomer parts provide superior chemical resistance and low contamination from extractables in pharmaceutical and food handling applications where FDA and/or USP <87> and <88> Class VI @ 121°C, compliance is required. DuPont™ Kalrez® 6230 parts are especially suited for Water for Injection (WFI) systems, Steam-in-Place (SIP) cleaning and other critical systems. Kalrez® 6230 are thermally stable up to 260°C (500°F), permitting them to be used in Stage II Sterilization processes, where other elastomers lose their sealing ability.

Product information

Color	Black
Maximum Service Temperature	260 ^[1] °C
Lowest Service Temperature	-20 ^[1] °C

[1]: DuPont proprietary test method; useful temperature range may vary with seal design and application specifics

Typical mechanical properties

Modulus at 100% elongation	9.6 MPa	ASTM D 412
Tensile Strength	16.5 MPa	ASTM D 412
Elongation at break	170 %	ASTM D 412
Shore A hardness	75	ASTM D 2240
Compression Set, 70h at 400°F, Pellet (Type 1)	25 %	ASTM D 395B
Compression Set, 70h at 400°F, O-ring (AS568-214)	26 %	ASTM D 1414

Thermal properties

Linear Coefficient of Thermal Expansion	2.89 E-4/°C	ISO 11359-1/-2
Retraction temperature, TR-10	-3 °C	ASTM D 1329

Other properties

Density	1.99 g/cm ³	ISO 1183
---------	------------------------	----------

Additional information

Material selection For more information on selecting the best Kalrez® product for your application, please consult the Kalrez® Application Guide (KAG). This software program and additional information on Kalrez® Perfluoroelastomer parts can be found at: kalrez.com

Revised: 2021-10-01

Page: 1 of 1

DuPont

The information set forth herein is furnished free of charge, is based on technical data that DuPont believes to be reliable, and represents typical values that fall within the normal range of properties. This information relates only to the specific material designated and may not be valid for such material used in combination with other materials or in other processes. It is intended for use by persons having technical skill, at their own discretion and risk. This information should not be used to establish specification limits nor used alone as the basis of design. Handling precaution information is given with the understanding that those using it will satisfy themselves that their particular conditions of use present no health or safety hazards and comply with applicable law. Since conditions of product use and disposal are outside our control, we make no warranties, express or implied, and assume no liability in connection with any use of this information. As with any product, evaluation under end-use conditions prior to specification is essential. Nothing herein is to be taken as a license to operate or a recommendation to infringe on patents.

CAUTION: Do not use DuPont materials in medical applications involving implantation in the human body or contact with internal body fluids or tissues unless the material has been provided from DuPont under a written contract or other acknowledgement that is consistent with the DuPont policy regarding medical applications and expressly acknowledges the contemplated use. For further information, please contact your DuPont representative.

DuPont's sole warranty is that our products will meet our standard sales specifications in effect at the time of shipment. Your exclusive remedy for breach of such warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted. TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, DUPONT SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY, OR NON-INFRINGEMENT. DUPONT DISCLAIMS LIABILITY FOR ANY SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES.

DuPont™, the DuPont Oval Logo, and all trademarks and service marks denoted with ™, SM or ® are owned by affiliates of DuPont de Nemours, Inc. unless otherwise noted.

© 2022 DuPont. All rights reserved.

Disclosure cat.:	I	proofread by:	Bi	publish date:	06/29/23	effect. date:	06/23
author:	MHe	released by:	Hes	replaces:	LID_DE_	status:	Published
resp. depart.:	M	date of release:	06/29/23	revision No.:	0		
doc. type:	LID	change rep. No.:	NA	retention period:	10y.	prot. class:	public



DuPont International Operations Sàrl
2, chemin du Pavillon
CH-1218 Le Grand-Saconnex / Geneva
Switzerland
Tel. : +41-22-717-6324

12th of February 2017

Leser GmbH & Co. KG
Elisa Röhl M.Sc.
Wendenstrasse 133-135
20537 Hamburg
Germany

Dear Mrs. Röhl,

European Regulation (EC) N° 1935/2004 was issued by the European Parliament and the Council of the European Union on 27th October 2004 for materials and articles intended to come into contact with food, repealing the European Directive 89/109/EEC. Article 3 of the Regulation requires that materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with Good Manufacturing Practice (GMP) so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- a) endanger human health
- b) bring about an unacceptable change in the composition of the food
- c) bring about a deterioration in the organoleptic characteristics thereof.

European Regulation (EC) N° 1935/2004 does include specific provisions relative to food contact for elastomers. There is a provision in European Regulation (EC) N° 1935/2004 that allows EU Member States to maintain national provisions, provided such provisions comply with the Treaty. Some Member States do maintain national provisions for specific measures relative to food contact for elastomers. At this time food contact compliance for above mentioned grades has not been established in those EU Member States which have specific measures relative to food contact for elastomers. Therefore, our product Kalrez® 6230 complies to the best of our knowledge to for to the European Regulation (EC) N° 1935/2004 (excluding Art. 5 and Art. 6).

Best Regards

Dr. Stefan Dully
Regulatory Affairs Manager

This statement is based on our current level of knowledge and covers commercial and experimental resins as supplied by DuPont at the date of issue. Since conditions of use are outside DuPont's control, DuPont makes no warranties, express or implied, and assumes no liability in connection with any use of this information.

* DuPont registered trademark

Disclosure cat.:	I	proofread by:	Bi	publish date:	06/29/23	effect. date:	06/23
author:	MHe	released by:	Hes	replaces:	LID_DE_	status:	Published
resp. depart.:	M	date of release:	06/29/23	revision No.:	0		
doc. type:	LID	change rep. No.:	NA	retention period:	10y.	prot. class:	public