



Angst+Pfister Group

Regulatory compliance

EHEDG World Congress

Christian Geubert // 12/13 Oct 2022

Seals in the process industry

Hygienic design

- Easy to clean
- Dead-space free
- Smooth surfaces

- Maximize the contact pressure of the seal to the food side

- Fool-proof design

- Mechanical stop and
- Mechanical guidance

- Prevention of pumping effects

Regulatory demands

- Europe
 - 1935/2004
 - 2023/2006
 - 10/2011
- USA
 - CFR 177.2600 (FDA)
 - 3A
- China
 - GB 4806.n
 - GB 9685
- Other countries
 - Mercosur
 - JP
- Additional (Atex, TSEfree,...)

Material resistance

- Chemical resistance
 - Starting materials and resulting products
 - Cleaning and sterilizing agents
 - Water and steam („normal“ and „cleaner“)
 - Resistant against migration of flavors, whether natural or artificial
- Mechanical resistance
 - Against abrasional products like soy, chocolate, nuts, seeds, and fruits like strawberries and blue berries

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Material resistance

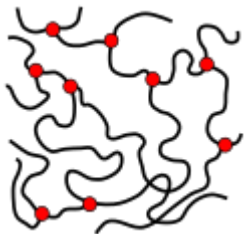
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Structure on a molecular level



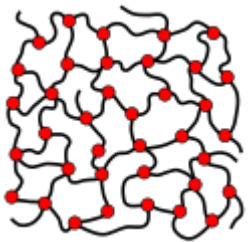
Thermoplastics

- Long linear macro molecules
- Can be melted again and again
- Cooling down in tool



Elastomers

- Widely meshed molecule chains
- Cannot be melted again
- Heating up in tool to start the curing
- Wide-meshed network to absorb and store energy leads to elasticity.

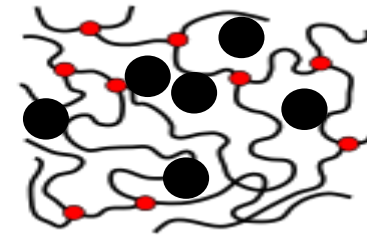


Thermosets or duroplasts

- Rigid cross-linking and high density of curing sites
- Once reaction is finished the material can only be reworked mechanically.

Base polymer and **Curing system** are two of the main ingredients.

Not forgetting the **Fillers**...



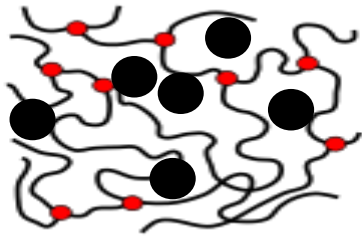
... but what about the **Softeners** here?

→ They are small!

The ingredients again...

Base polymer and **Curing system** are two of the main ingredients.

Not forgetting the **Fillers**...



... but what about the **Softeners** here?

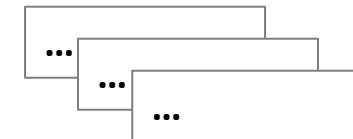
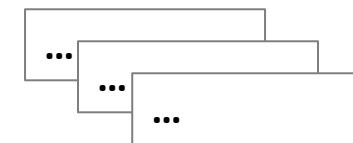
- **Base polymer**
- **Curing system**
 - Curing agents
 - Accelerators
 - Retarders
- **Fillers...**
 - Black or white?
 - Active or non-active?
- **Softeners? Or better not?**
- **„The small chemistry“ or the „Know-How“**
 - Production aids
 - Ageing inhibitors
 - Ozone protecting waxes
 - Colours

Elastomers

- NR
- NBR
- HNBR
- EPDM
- CR
- VMQ
- FKM
- FFKM

Suppliers

- The Dow Chemical Company
 - ExxonMobil
 - Lion Elastomers
 - LANXESS
 - MITSUI CHEMICALS
- + small local and regional ones



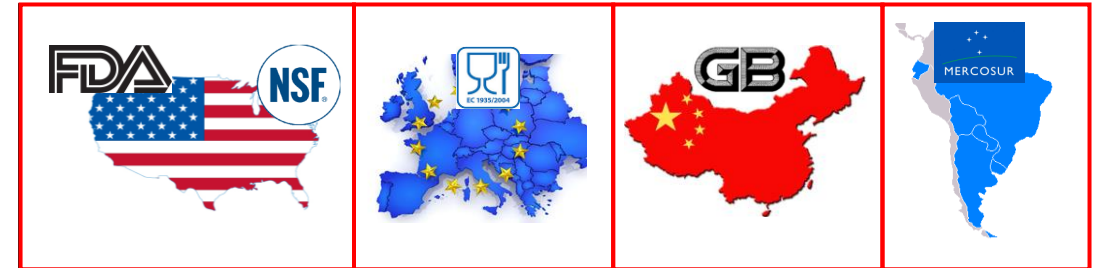
The jungle of approvals



PERTEC® Compounds for Food & Beverage applications

Needed approvals for the Food & Beverage Industry including PAH Class 1:

- FDA 21 CFR 177.2600 a) – f)
- NSF 51 for food
- 3A Sanitary standard no 18-03
- EC 1935/2004 article 3 (MOCA, Italy)
- GB 4806.1-2016, GB 9685-2016, GB 4806.11-2016
- Mercosur GMC 03/92, GMC 28/99, GMC 54/97



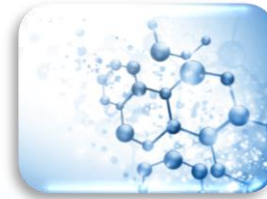
Approvals	PERTEC® UP FKM 70.501-07	PERTEC® CIP FKM 75.501-04	PERTEC® UP VMQ 70.501-01
Food & Beverage	FDA 21 CFR 177.2600 a) - f) NSF 51 for food 3A Sanitary standard no 18-03 Class 1	FDA 21 CFR 177.2600 a) - f) NSF 51 for food 3A Sanitary standard no 18-03 Class 1	FDA 21 CFR 177.2600 a) - f) NSF 51 for food 3A Sanitary standard no 18-03 Class 1
	EC 1935/2004 article 3 - BfR XXI Class 4 - Germany - LFGB § 30/31 - Germany - French Arreté 09/11/1994 - France - SR 817.023.21 - Switzerland	EC 1935/20014 article 3 - BfR XXI Class 4 - Germany - LFGB § 30/31 - Germany - French Arreté 09/11/1994 - France - SR 817.023.21 - Switzerland - D.M. 21/03/1973 - Italy	EC 1935/20014 article 3 - BfR XV - Germany - LFGB § 30/31 - Germany - French Arreté 25/11/1992 - France - SR 817.023.21 - Switzerland - D.M. 21/03/1973 - Italy
	GB 4806.11-2016 (Migration test)	GB 4806.11-2016 (Migration test)	GB 4806.11-2016 (Migration test) GB 9685-2016 (Positiv list) GB 4806.1-2016 (Food law)
			Mercosur GMC 28/99 (Positiv list)
Drinking water	UBA Elastomer-Guidline cold water (23°C) hot water (85°C) DVGW W 270	-	KTW-Guidline cold water (23°C) hot water (85°C) DVGW W 270
Others	PAH Class 1 (AfPS GS 2014:01) PAHs requirements according Regulation (EU) No 1272/2013 BAM approved maximum temperature 150 °C, maximum oxygen pressure 30 bar	PAH Class 1 (AfPS GS 2014:01) PAHs requirements according Regulation (EU) No 1272/2013 USP Class VI Ch. 87 and Ch. 88, 121°C	PAH Class 1 (AfPS GS 2014:01) PAHs requirements according Regulation (EU) No 1272/2013 USP Class VI Ch. 87 and Ch. 88, 121°C DVGW EN 549 D2 H3 -20°C to +125°C

Global approvals



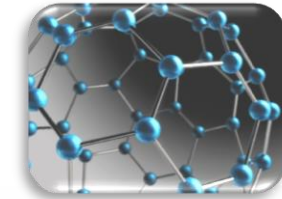
PERTEC® UP VMQ

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- D.M. 21/03/1973
- GB 4806.1-2016 (Food law)
- GB 4806.11-2016 (Migration test)
- GB 9685-2016 (Positive list)
- Mercosur GMC 28/99 (Positive list)
- PAH Class 1 (AfPS GS 2019:01)
- PAHs according (EU) No 1272/2013
- USP Class VI Chapter <87> (In Vitro) and Chapter <88> (In Vivo) - 121°C



PERTEC® UP FKM

- FDA 21 CFR 177.2600 a) - f)
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- COGNAC (Wine spirits, France)



PERTEC CIP/SIP FKM

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Many thanks!

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