

Declaration of Compliance

ECON Premium ball valves Fig. 7442, 7542, 7642 and 7742



Eriks Flow Control herewith declares that the above mentioned ball valves meet the requirements as defined in:

- European Regulation (EC) No. 1935/2004 (Food Contact Materials)
- European Regulation (EC) No. 2023/2006 (Good Manufacturing Practice)
- FDA 21 CFR 177.1550 (Perfluorocarbon resins)

Product: Stainless steel 3-piece ball valve, figure numbers: 7442, 7542, 7642 and 7742

The body, ball, stem and seats are the only valve parts intended to come in contact with food.

Migration test results stainless steel valve parts

- Body (ASTM A351-CF8M)
- Ball (ASTM A351-CF8M)
- Stem (AISI-316)

Migration test protocol according to CM/Res(2013)9, Specific release of Metals

Method	Parameter	Analysis principle	Migration conditions for the 3 successive migration steps	Result
EPA 3052 mod	Preparation for migration (metals)	Exposure to 0,5% citric acid by article filling ICP-MS	1 hour / 100°C	Pass

Report: 392-2017-00192401ver2_MP_EN

Migration test results PTFE seats

Migration test protocol according to EU 10/2011 (EN1186), Overall Migration

3M Dyneon TF 4103 seats (repeated use)					
Food simulant	Contact foods	Migration conditions	Technique	OML-value (mg/dm ²)	Result
A - Ethanol 10%	Aqueous food	3 x 4 hours / 100° C	Immersion	< 10	Pass
B - Acetic acid 3%	Acidic food	3 x 4 hours / 90° C	Immersion	< 10	Pass
D2 - Olive oil	Fatty food	4 hours / 100° C 8 hours / 100° C 12 hours / 100° C	Immersion	< 10	Pass

Report No.: 392-2023-00599301_MP_EN

3M Dyneon TF 4215 seats					
Food simulant	Contact foods	Migration conditions	Technique	OML-value (mg/dm ²)	Result
A - Ethanol 10%	Aqueous food	4 hours / 100° C	Immersion	< 10	Pass
B - Acetic acid 3%	Acidic food	4 hours / 100° C	Immersion	< 10	Pass
D2 - Olive oil	Fatty food	4 hours / 80° C	Immersion	< 10	Pass

Report No.: 392-2017-00300701_MP_EN

3M Dyneon TFM 1600 seats (repeated use)					
Food simulant	Contact foods	Migration conditions	Technique	OML-value (mg/dm ²)	Result
A - Ethanol 10%	Aqueous food	3 x 4 hours / 100° C	Immersion	< 10	Pass
B - Acetic acid 3%	Acidic food	3 x 4 hours / 90° C	Immersion	< 10	Pass
D2 - Olive oil	Fatty food	4 hours / 100° C 8 hours / 100° C 12 hours / 100° C	Immersion	< 10	Pass

Report No.: 392-2023-00599302_MP_EN

Migration test protocol according to EU 10/2011 (EN1186), Specific Migration (based on cube assumption - 6 dm² per kg food)

3M Dyneon TF 4103 seats			
Parameter		SML-value (mg/kg)	Result
Tetrafluoroethylene (TFE)	Worst case calculation of migration	< 0,05	Pass
Perfluoropropoxethylene	Worst case calculation of migration	< 0,05	Pass

Report No.: 392-2023-00599301_MP_EN

3M Dyneon TF 4215 seats			
Parameter		SML-value (mg/kg)	Result
Tetrafluoroethylene (TFE)	Worst case calculation of migration	< 0,05	Pass

Report No.: 392-2017-00300701_MP_EN

3M Dyneon TFM 1600 seats			
Parameter		SML-value (mg/kg)	Result
Tetrafluoroethylene (TFE)	Worst case calculation of migration	< 0,05	Pass
Perfluoropropoxethylene	Worst case calculation of migration	< 0,05	Pass

Report No.: 392-2023-00599302_MP_EN

Extraction test method according to FDA 21 CFR 177.1550, overall extraction

3M Dyneon TF 4103 seats			
Test	Migration conditions	Requirements (mg/inch ²) *	Result
Extraction in Heptane 2 hours	2 hours / 100° C	Max. 0,2	Pass
Extraction in Water 2 hours	Reflux temp. for 2 hours	Max. 0,2	Pass
Extraction in 50% Ethanol 2 hours	2 hours / 100° C	Max. 0,2	Pass
Extraction in ETAC 2 hour supplementary	Reflux temp. for 2 hours	Max. 0,2	Pass

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* as mentioned in FDA 21 CFR 177.1550

3M Dyneon TFM 1600 seats			
Test	Migration conditions	Requirements (mg/inch ²) *	Result
Extraction in Heptane 2 hours	2 hours / 100° C	Max. 0,2	Pass
Extraction in Water 2 hours	Reflux temp. for 2 hours	Max. 0,2	Pass
Extraction in 50% Ethanol 2 hours	2 hours / 100° C	Max. 0,2	Pass
Extraction in ETAC 2 hour supplementary	Reflux temp. for 2 hours	Max. 0,2	Pass

Report No.: 392-2023-00599302_MP_EN

* as mentioned in FDA 21 CFR 177.1550

Migration test results PEEK seats - Solvay KetaSpire KT-820 NT seats

Migration test protocol according to EU 10/2011 (EN1186), Overall Migration (repeated use)

Food simulant	Contact foods	Migration conditions	Technique	OML-value (mg/dm ²)	Result
A - Ethanol 10%	Aqueous food	3 x 4 hours / 90° C	Immersion	< 10	Pass
B - Acetic acid 3%	Acidic food	3 x 4 hours / 100° C	Immersion	< 10	Pass
D2 - Olive oil	Fatty food	2 hours / 175° C 4 hours / 175° C 6 hours / 175° C	Immersion	< 10	Pass

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Migration test protocol according to EU 10/2011 (EN1186), Specific Migration

Parameter	Food simulant	Migration tests	SML-value (mg/kg)	Result
Hydroquinon	A - 10% Ethanol	3 times	< 0,6	Pass
4,4-difluorobenzophenone	D2 - 95% Ethanol	3 times	< 0,05	Pass
Diphenyl sulfone	D2 - 95% Ethanol	3 times	< 3	Pass

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Extraction test method according to FDA 21 CFR 177.1550, overall extraction

Test	Migration conditions	Requirements (mg/inch ²)	Result
Extraction in Distilled water	Reflux temp. for 2 hours	< 0,2	Pass
Extraction in 50% Ethanol	Reflux temp. for 2 hours	< 0,2	Pass
Extraction in Ethyl acetate	Reflux temp. for 2 hours	< 0,2	Pass
Extraction in n-heptane	Reflux temp. for 2 hours	< 0,2	Pass

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