

DONIFLEX® GASKET MATERIAL ARTICLES: Compliance with REACH & OTHER REGULATIONS

Updated: 14 NOV 2024



STATEMENT: We hereby certify that, to the best of our knowledge,

DONIFLEX® articles –manufactured by DONIT, Slovenia, EU– are composite materials of different chemical substances that individually comply with REACH and the tabulated regulations (see *Table*) considering the latest amendments (see *this version date*). Consequently, **the title articles as such comply to date with the said regulations.**

Please also refer to the articles' corresponding "Article Safety Data Sheet (ASDS)", "Storage & Handling" and "DONIT Statement for California Proposition 65 (CP65)" publications.

DONIFLEX® Articles Composition:

The common constituents of these articles are inorganic fillers (i.e. graphite [CAS 7782-42-5], amorphous silicon dioxide [CAS 69012-64-2]), fibers (i.e. aramid [CAS 26125-61-1], carbon [CAS 308063-56-1]), acrylonitrile-butadiene rubber [CAS 9003-18-3], and with a version containing a reinforcement insert of expanded stainless-steel (AISI 316L), and other versions with IQ, graphite, or fluoropolymers anti-stick surface finish.

No listed substance, if any at all, is present above the allowed threshold / is below the safe harbor level.

REGULATION (with amendments to date)	(if any) Level of Listed Chemical Substance	DONIFLEX® Articles		
		Plain material	with metal reinforcement	with anti-stick finish*
REACH ¹	<i>Absent - Not Applicable</i>	<i>Compliant</i>	<i>Compliant</i>	<i>Compliant</i>
SVHC ²	<i>Absent - Not Applicable</i>	<i>Compliant</i>	<i>Compliant</i>	<i>Compliant</i>
PAH ³	<i>Absent - Not Applicable</i>	<i>Compliant</i>	<i>Compliant</i>	<i>Compliant</i>
ODS ⁴	<i>Absent - Not Applicable</i>	<i>Compliant</i>	<i>Compliant</i>	<i>Compliant</i>
POP ⁵	<i>Absent - Not Applicable</i>	<i>Compliant</i>	<i>Compliant</i>	<i>Compliant</i>
RoHS 3 ⁶	<i>Absent - Not Applicable</i>	<i>Compliant</i>	<i>Compliant</i>	<i>Compliant</i>
BSE TSE ⁷	<i>Absent - Not Applicable</i>	<i>Compliant</i>	<i>Compliant</i>	<i>Compliant</i>
PBT ⁸	<i>Absent - Not Applicable</i>	<i>Compliant</i>	<i>Compliant</i>	<i>Compliant</i>
CP65 ⁹	<i>Absent - Not Applicable</i>	<i>Compliant</i>	<i>Compliant</i>	<i>Compliant</i>
* Articles with fluoropolymers anti-stick: PFAS ¹⁰	<i>PFOA, its salts & PFOA related compounds - Absent</i>	<i>Compliant</i>		

1. REACH – European Chemicals Agency (ECHA): Regulation (EC) No 1907/2006.
2. Substances of Very High Concern (SVHC) – REACH Candidate List; Authorization (Annex XIV); Restriction (Annex XVII). Consequently, no reporting is required to the SCIP database according to the Waste Framework Directive (EU) 2018/851.
3. Polycyclic Aromatic Hydrocarbons (PAHs): Annex XVII of REACH.
4. Ozone Depleting Substances (ODS) – Montreal Protocol: Regulation (EC) No 1005/2009.
5. Persistent Organic Pollutants (POPs) – Stockholm Convention: Regulation (EU) 2019/1021 (recast), Annexes I & III, and Regulation (EU) 2021/277.
6. Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS 3): Regulation (EU) 2011/65, and 2015/863.
7. Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE) causing agents; European Food Safety Authority (EFSA).
8. Persistent, Bioaccumulative, and Toxic (PBT) Chemicals – U.S. Environmental Protection Agency (EPA), Toxic Substances Control Act (TSCA): Section 6(h).
9. California Proposition 65 (CP65) – The Safe Drinking Water and Toxic Enforcement Act of 1986: www.P65Warnings.ca.gov
10. Per- and polyfluoroalkyl substances (PFAS): Regulation (EU) 2017/1000, 2019/1021, and 2021/115.

Medvode, Slovenia - EU, for DONIT TESNIT d.o.o.:

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