

OECD polymer of low concern (PLC) criteria add © 2021 W.L. Gore Associates

OECD = Organisation for Economic Co-operation and Development

Polymer	Polymer composition	MW, Mn, MWD	Wt-% oligomer	Electrical charge	Reactive functional groups (RFG)
T8	✓	✓	✓	✓	✓
T4	✓	✓	✓	✓	✓
T8W	✓	✓	✓	✓	✓
T4W	✓	✓	✓	✓	✓
E4W	✓	✓	✓	✓	✓
E8W	✓	✓	✓	✓	✓
Soft P2	✓	✓	✓	✓	✓
P2	✓	✓	✓	✓	✓
FKM	✓	✓	✓	✓	✓
FFKM	✓	✓	✓	✓	✓
FEPM	✓	✓	✓	✓	✓
ECTFE	✓	✓	✓	✓	✓
Fluoropolymer					
PTFE	✓	✓	✓	✓	✓
TFM-PTFE	✓	✓	✓	✓	✓
PFA	✓	✓	✓	✓	✓
FEP	✓	✓	✓	✓	✓
Alternative Materials					
PEEK	✓	✓	✓	✓	✓
PAEK	✓	✓	✓	✓	✓
PPS	✗	✓	✗	✓	✓
PI	✗	✓	✗	✓	✓
PAI	✗	✓	✗	✓	✓

Symbols



Legend

Polymer composition	Polymer composition, structure & elemental composition; including CAS no.
MW, Mn, MWD	Number average molecular weight and oligomer content are used criteria for P
Wt-% oligomer	Weight % of oligomers < 1000 Da
Electrical charge	El. Ch. or ionic character can be: anionic, cationic, amphoteric, nonionic; cationi
Reactive functional groups (RFG)	Atom or associated group of atoms in a chemical structure that is intended or c
Functional group equivalent weight (FGEW)	FGEW is defined as the ratio of Mn to the number of functional groups in the p
Low MW leachables	Are chemical molecules, either inorganic or organic, that migrate (i.e. leach) ou
Water/lipid solubility, octanol water partition	Water solubility = extent to which a compound will dissolve in water; negligible

Particle size	Particles that are small enough to reach the deep lung upon inhalation are asso
Polymer stability	Resistance to physical, chemical, biological transformation. Breaking down into
Thermal stability	To be assessed when used as intended or in extreme temperature during dosp
Abiotic stability	Polymers are stable, monomers are not. Abiotic degradaton may involve sunlig
Biotic stability	Is assessed by whether the polyymmer is degraded by microorganisms under oxy

associated with adverse health effects. Polymer particles should be $> 5 \mu\text{m}$
smaller particles is critical. Molecules with $M_n < 1000 \text{ Da}$ are capable of crossing cell membranes
osal. Thermal stability testing may involve TGA
ht, water or oxygen.
generated (aerobic) or anoxic (anaerobic) conditions

Abiotic stability Biotic stability Coeff of Friction Chemical Compatibility

✓	✓	✓	✓
✓	✓	✓	✓
✓	✓	✓	✓
✓	✓	✓	✓
✓	✓	✓	✓
✓	✓	✓	✓
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✓	✓	✓	✗