ALBIS

Taking care of your health.

Healthcare Polymer Solutions

		REGULATORY COMPLIANCE			STERILISATION COMPATIBILITY						
		BIOCOMPATIBILITY		DMF/MAF LISTING	AUTOCLAVE			IRRADIATION		GAS	TRANSPARENT AVAILABLE
		USP CLASS VI	ISO 10993		121 °C	134 °C	143 °C	GAMMA	E-BEAM	ETHYLENE OXIDE	
BASF											
Ultraform® PRO AT	POM	✓	✓	DMF ✓	✓	(✓)	–	(✓)	(✓)	(✓)	–
Ultradur® PRO	PBT	✓	✓	DMF ✓	(✓)	–	–	✓	✓	✓	–
covestro											
Makrolon®	PC	(✓)	(✓)	DMF (✓)	✓	–	–	(✓)	(✓)	✓	✓
Apec®	PC-HT	(✓)	(✓)	–	✓	✓	✓	(✓)	(✓)	✓	✓
Bayblend® M	PC/ABS	✓	✓	–	–	–	–	(✓)	(✓)	✓	–
Makroblend® M	PC/PBT	–	(✓)	–	–	–	–	(✓)	(✓)	✓	–
Texin®	TPU	(✓)	(✓)	DMF (✓)	–	–	–	✓	✓	✓	(✓)
INEOS STYROLUTION											
Luran® HD	SAN	✓	✓	DMF ✓	–	–	–	✓	✓	✓	✓
Terlux® HD	MABS	✓	✓	DMF ✓	–	–	–	✓	✓	✓	✓
Novodur® HD	ABS	✓	✓	DMF ✓	–	–	–	✓	✓	✓	–
NAS®	SMMA	✓	✓	DMF ✓	–	–	–	✓	✓	✓	✓
Zylar®	MBS	✓	✓	DMF ✓	–	–	–	✓	✓	✓	✓
Styrolux®	SBC	✓	✓	DMF ✓	–	–	–	✓	✓	✓	✓
K-Resin®	SBC	(✓)	(✓)	DMF (✓)	–	–	–	✓	✓	✓	✓
Styroflex®	S-TPE	✓	✓	DMF ✓	–	–	–	✓	✓	✓	✓
lyondellbasell											
Purell®	PP	✓	✓	DMF ✓	✓	–	–	(✓)	(✓)	✓	(✓)
Purell®	PE	✓	✓	DMF ✓	(✓)	–	–	✓	✓	✓	–
Purell® KT MR07	PB-1	✓	✓	DMF ✓	✓✓	–	–	NT	NT	NT	✓✓
SK chemicals											
SKYPET®	PET(g)	(✓)	–	DMF (✓)	–	–	–	(✓)	(✓)	(✓)	✓
ECOZEN®	Bio-modified Copolyester	(✓)	–	–	–	–	–	(✓)	(✓)	(✓)	✓
SKYGREEN®	PETG / PCTG	(✓)	–	DMF (✓)	–	–	–	(✓)	(✓)	(✓)	✓
alphagary											
Evoprene® R 9900 series	TPE	(✓)	(✓)	DMF (✓)	(✓)	–	–	(✓)	(✓)	(✓)	–
SOLVAY											
IXEF® HC/GS	PARA	–	(✓)	MAF (✓)	✓	(✓)	–	✓	✓	✓	–
MOCOM											
Alcom® MED - Healthcare Compounds		Alcom® MED offers customer-lead solutions for medical devices, pharmaceutical packaging and diagnostic applications. Compounds can be coloured, functional or both depending upon specific customer needs across various polymer types. Alcom® MED product service offering can include based on customer agreement, inter alia, compositional statements, change notification periods, regulatory compliance statements and production on an ISO 13485 - certified production facility.									

✓ Materials fulfill requirements

(✓) Limited fulfillment or only designated grades

– Materials do not fulfill requirements

✓✓ Depending upon the mixing concentration in a PP blend

NT Not tested

® = Registered Trademark

TM= Trademark

DMF = Drug Master File

MAF = Master Access File

The product range may vary by region.

Important note

Healthcare uses: The supply of any product by ALBIS for any medical, pharmaceutical or diagnostic application is conditional to an assessment by ALBIS in terms of compliance with ALBIS' internal risk management policy – even for products which are in general designated for use in Healthcare applications.

Important: Irrespective of product type or designation, ALBIS does not recommend or support the use of any products it supplies which fall into the following medical, pharmaceutical or diagnostic application categories:

- Medical devices categorized as risk class III according to EU Medical Device Regulation (MDR) 2017/745 or risk class 3 FDA
- Medical devices described in list A according IVDD (98/79/EG) or risk class D in EU 2017/746 in vitro diagnostic medical devices (IVDR)
- Bodily implant applications for greater than 30 days (permanent implants) in any risk class
- Critical components in any medical device that supports or sustains human life

except as otherwise explicitly agreed by ALBIS in writing.

Disclaimer

Any information given on the chemical and physical characteristics of our products, including, without limitation, technical advice on applications, whether verbally, in writing or by testing the product, is given to the best of our knowledge and in good faith and does not exempt the buyer from carrying out their own investigations and tests in order to ascertain the product's specific suitability for the purpose intended. The buyer is solely responsible for confirming the suitability of the product for a particular application, its utilization and processing and must observe any applicable laws and government regulations.

No express or implied recommendation or warranty is given with regard to the suitability of the product for a particular application, such as, but not limited to, safety-critical components or systems.

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