INEOS STYROLUTION

REGULATORY COMPLIANCE
FULL SERVICE HD PACKAGE ENHANCED

	Novodur® HD 15	Novodur® HD M203FC Natural	Novodur® HD M203FC G3 Natural	Lustran® ABS 248 FC	Lustran® ABS 348
DMF TYPE III – Packaging Material	18858	15885	15885	14806	13048
LETTER OF AUTHORIZATION	*Issued on request*				
PHARMACOPOEIA & BIOCOMPATIBILITY	✓ **Europe**: EUP, 7th Edition, Chap. 3.2.2. "Plastic Containers and Closures" ✓ **Japan:** JP, 16th Edition, "G7. Plastic Containers for Pharmaceutical Products" ✓ **US**: USP Class VI Biological Reactivity Tests ✓ **ISO 10993-4**: Biocompatibility tests for in vitro hemolysis ✓ **ISO 10993-5**: Biocompatibility tests for cytotoxicity				
FOOD CONTACT [1]	✓ Regulation (EU) No.10/2011 statement [2] ✓ FDA (US) statement				

[1] The food contact statements for the above mentioned products can include restrictions of use. For more information, please contact your sales representative.
[2] For Lustran® 348 under assessment

Please note: The above listed grades are also available in pre-colored versions, some of which are listed in the Drug Master Files and have been or are being assessed according to the above mentioned regulations. For more information, please contact your sales representative.

The above tests and classifications were recorded on test specimens of the mentioned grades to provide information on the general compatibility of the material. These do not form a specification or warranty. The biocompatibility tests and certain other tests (e.g. residual levels on moulded plaques) referred to above are not part of any continuous production control. The suitability (fit for purpose) for any specific application concerned, including observation of given limitations and toxicological thresholds according to medical, pharmaceutical and/or food contact requirements, have to be ensured on the final article by the article manufacturer.

INEOS STYROLUTION

REGULATORY COMPLIANCE
FULL SERVICE HD PACKAGE

TRANSPARENT

	Luran® HD 20	Terlux® HD 2802	Terlux® HD 2812	Terlux® HD 2822
DMF TYPE III – Packaging Material	21885	18074	20017	25140
LETTER OF AUTHORIZATION	*Issued on request*			
PHARMACOPOEIA & BIOCOMPATIBILITY	✓ **Europe**: EUP, 7th edition, Chap. 3.2.2. "Plastic Containers and Closures" ✓ **Japan**: JP, 16th edition,"G7. Plastic Containers for Pharmaceutical Products" ✓ **US:** USP Class VI Biological Reactivity Tests ✓ **ISO 10993-4**: Biocompatibility tests for in vitro hemolysis ✓ **ISO 10993-5**: Biocompatibility tests for cytotoxicity			
FOOD CONTACT[1]	✓ Regulation (EU) No.10/2011 statement ✓ FDA (US) statement			

[1] The food contact statements for the above mentioned products can include restrictions of use. For more information, please contact your sales representative.

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INEOS STYROLUTION

REGULATORY COMPLIANCE ESSENTIAL HD PACKAGE

	Clearblend® 145, 155, 165	NAS® 21, 30, 90	Styrolux® 656C, 684D, 3G46, 4G60	Styroflex® 2G66, 4G80	Zylar® 245, 550, 631*, 650, 765, 960	Lustran® SAN 31, 29, Sparkle	K-Resin® KR01, KR03, KR05, DK11
DMF TYPE III – Packaging Material	31639 LOA on request	29425 LOA on request	656C: 17772 684D: 17771 3G46: 30956 4G60: 31741 LOA on request	*Under development*	*30812* LOA on request	13096 LOA on request	2406 LOA on request
PHARMACOPOEIA & BIOCOMPATIBILITY	✓ **Europe**: EUP, 7th Edition, Chap. 3.2.2. "Plastic Containers and Closures" ✓ **Japan:** JP, 16th Edition, "G7. Plastic Containers for Pharmaceutical Products" ✓ **US**(2): USP Class VI Biological Reactivity Tests ✓ **ISO 10993-4**(2): Biocompatibility tests for in vitro hemolysis ✓ **ISO 10993-5**(2): Biocompatibility tests for cytotoxicity						
FOOD CONTACT(1)	✓ Regulation (EU) No.10/2011 statement(2) ✓ FDA (US) statement(2)						

(1) The food contact statements for the above mentioned products can include restrictions of use. For more information, please contact your sales representative.
(2) For Styroflex® under assessment
* Only US produced Zylar 631 is offered with the Essential HD package.

Please note: This "Essential HD" portfolio is a newly created product list which is continuously being updated. Hence, please always contact your sales representative at INEOS Styrolution for the latest regulatory status of the products of interest.

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