SK Chemicals Co., Ltd
310 Pangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do 463-400 Korea
Emergency Tel. No. : 82-2-2008-2292

[RIS-2014-30] **ver. 01. 14/06/10**

Regulatory Information Sheet

SKYGREEN S2008 – Medical

SK Chemicals' PETG resin, designated as SKYGREEN S2008, complies with the following medical-related regulations.

1. ISO 11607-1: 2006

SKYGREEN S2008 is in subjective compliance to ISO 11607-1: 2006 / EN ISO 11607-1: 2009, as it applies to raw material and not the finished device. Below is a table that shows the tests conducted to show compliance to ISO 11607-1: 2006.

Test	Pre-sterilization	Post-sterilization	Accelerated Aging (5 years)
Biocompatibility Testing, including: • USP Intracutaneous Reactivity • USP Acute Systemic Toxicity • USP Implantation • Cytoxicity (ISO 10993) • Sensitization (ISO 10993) • Hemocompatibility (ISO 10993)	Not required	Tested for: • EtO • Gamma 15kGy • Gamma 55kGy	Not required
Chemical Testing, including: • USP Physicochemical Test – Plastics <661>, Aqueous Extraction in Purified Water (PW) for Total Non-Volatile Residue (NVR), Residue on Ignition (ROI), Heavy Metals (HM) and Buffering Capacity (BC) • USP Physicochemical Test – Plastics <661>, Alternate Extract in Ethanol (EtOH) for Non-Volatile Residue, Residue on Ignition, Turbidity and UV	Tested	Tested for: • EtO • Gamma 15kGy • Gamma 55kGy	Tested for: • EtO • Gamma 15kGy • Gamma 55kGy

SK Chemicals Co., Ltd
310 Pangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do 463-400 Korea
Emergency Tel. No. : 82-2-2008-2292

Absorption. • Infrared analysis of extract residues (PW and EtOH) • Infrared analysis of the Test Article • Gas Chromatography with Mass Spectrometry (GC/MS) of extract residues (PW and EtOH) • Differential Scanning Calorimetry (DSC) Characterization			
Physical Testing (per AAMI TIR17:2008), including: • Tensile properties • Flexural properties • Impact resistance • Hardness • Tear strength • Discoloration	Required	Tested for: • EtO 1 cycle • EtO 2 cycles • E-beam 55kGy • Gamma 15kGy • Gamma 55kGy	Tested for: • EtO 1 cycle • EtO 2 cycles • E-beam 55kGy • Gamma 15kGy • Gamma 55kGy

2. ISO 10993

SK Chemicals' PETG copolyester resin, designated as SKYGREEN S2008, complies with ISO 10993 guidelines. Test results of SKYGREEN S2008 are shown in the below table.

Test	ISO Guideline	Method	Results
Cell Cytotoxicity	ISO 10993 Part 5	MEM Extraction	**Pass**
Ames Genotoxicity	ISO 10993 Part 3	Saline	**Pass**
Hemocompatibility	ISO 10993 Part 4	Direct Contact	**Pass**
Irritation	ISO 10993 Part 10	Intracutaneous saline/Cottonseed/PET/ETOH	**Pass**
Sensitization		Guinea Pig Maximization	**Pass**
Systemic Toxicity	ISO 10993 Part 11	Acute	**Pass**
		14 day Repeat Dose	
Implant	ISO 10993 Part 6	2 week Intramuscular	**Pass**

3. USP Class VI

The testing of the material has shown that SKYGREEN S2008 is safe for use in medical device packaging for terminal sterilization and has met USP Class VI certification.

SK Chemicals Co., Ltd
310 Pangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do 463-400 Korea
Emergency Tel. No. : 82-2-2008-2292

4. USP <661>

SK Chemicals' PETG resin, designated as SKYGREEN S2008, complies with the compositional requirements and specifications of USP <661> Containers – Plastics.

SKYGREEN S2008 was tested against all components of the USP <661> requirements, including multiple internal reflectance, thermal analysis, water vapor permeation, color extraction, heavy metals, and absorbance @ 575 nm against ethylene glycol. It was found acceptable in all tests and thus meets all the requirements of USP <661>.

SK Chemicals' SKYGREEN S2008 may be used in contact with solid and liquid pharmaceutical dosage forms, except where its use would be inappropriate, such as for heat sterilization or where solvents attack the resin. Therefore, it is the responsibility of our customers to determine that their use of our products is safe, lawful, and technically suitable in their intended applications.

5. Drug Master File (DMF)

SK Chemicals' PETG resin, designated as SKYGREEN S2008, has DMF (Drug Master File) number 16525 filed with the U.S. FDA as Type Ⅲ: Packaging Material. The DMF certification letter can be searched at:

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/default.htm

As the conditions or methods of use are beyond our control, we do not assume any responsibility and expressly disclaim any liability for any use of this material. Thus, customers take the responsibility to determine that the use of our product is safe and lawful in their intended applications. Possibilities for changes not only in law and regulations but also in our products make it difficult for us to guarantee that the status of this product will remain unchanged. Due to this reason, we recommend that customers verify its status periodically.

For additional information, please contact your SK Chemicals sales representative or SK Chemicals marketing subsidiary.