

**Regulatory Affairs Product Stewardship Information/Certification Data Sheet**  
**SKYGREEN® PETG S2008**

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

**1. Chemical Inventories (Chemical Control Laws)**

• **Europe**

**REACH (Registration, Evaluation, Authorization and Restriction of Chemicals)**

The substances contained in SKYGREEN® PETG S2008 are registered in accordance with REACH legislation.

• **USA**

**TSCA (Toxic Substances Control Act)**

SKYGREEN® PETG S2008 complies with TSCA polymer exemption regulation. The exempted polymer is not listed on the TSCA Inventory.

• **Canada**

**DSL (Domestic Substances List)**

SKYGREEN® PETG S2008 is listed on the DSL.

• **Korea**

**KECI/KECL (Korea Existing Chemicals Inventory/List)**

SKYGREEN® PETG S2008 complies with K-REACH polymer exemption regulation. SKYGREEN® PETG is an existing chemical substance under K-REACH and listed in KECI/KECL.

• **Japan**

**ENCS (Existing and New Chemical Substances)**

SKYGREEN® PETG S2008 is listed on the Japanese ENCS.

• **China**

**IECSC (Inventory of Existing Chemical Substances in China)**

SKYGREEN® PETG S2008 is listed on the IECSC.

• **Taiwan**

**TCSI (Taiwan Chemical Substance Inventory)**

SKYGREEN® PETG S2008 is listed on the TCSI and phase I registration was completed through Taiwan importers.

• **Australia**

**AICS (Australian Inventory of Chemicals List)**

SKYGREEN® PETG S2008 is listed on AICS.

**2. Substances of Very High Concern (SVHC) under Regulation (EC) No 1907/2006 concerning REACH**

SK Chemicals' PETG S2008 resin, designated as SKYGREEN® PETG S2008, complies with the latest version (updated 16 January, 2020) of Candidate List of Substances of Very High Concern (SVHC), which is published in accordance with Article 59(10) of the REACH Regulation by ECHA.

The updated candidate list of SVHC can be found at: <http://echa.europa.eu/candidate-list-table>

SKYGREEN® PETG S2008 resin does not contain any of the substances listed in the Candidate List in a concentration above 0.1 % weight by weight (w/w).

### 3. Food Contact

- **Europe**

Based on the information available and the testing outlined below, the product, SKYGREEN® PETG S2008, as supplied by SK Chemicals Co., Ltd. is in compliance with the below regulations for use with all foods types at long term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to a temperature T where  $70\text{ }^{\circ}\text{C} \leq T \leq 100\text{ }^{\circ}\text{C}$  for a maximum of  $t = 120/2^{((T-70)/10)}$  minutes. The manufacturing of SKYGREEN® PETG S2008, that are sold as food contact grades, complies with EU Commission Regulation (EC) No 2023/2006, based upon the audit completed by Third-party company from a QA, QC, and product safety assurance perspective on September 20, 2018.

- **USA**

SK Chemicals' PETG S2008 resin, designated as SKYGREEN® PETG S2008, complies with the compositional requirements and specifications of the U.S. Food and Drug Administration (FDA) regulation 21 CFR 177.1315(b)(1). Based on the extraction studies on the articles fabricated from SKYGREEN® PETG S2008, SK Chemicals concludes that this resin may be safely used in contact with foods containing not more than 25 percent by volume aqueous alcohol, excluding carbonated beverages and beer. Conditions of hot fill not to exceed 82.2 °C, and storage at temperatures not in excess of 48.9 °C are allowed. Hot treatment should not be performed when foods are in containers.

- **Japan**

SK Chemicals' PETG S2008 resin, designated as SKYGREEN® PETG S2008, complies with the requirements and specifications of Japan Hygienic Olefin and Styrene Plastic Association (JHOSPA).

- **China**

Chinese National Health and Family Planning Commission (NHFPC) approves SKYGREEN® PETG as a new food contact resin which can be safely used in contact with foods containing not more than 25 % (by volume) aqueous alcohol, excluding carbonated beverages and beer. Conditions of hot fill not to exceed 82.2 °C, and storage at temperatures not in excess of 48.9 °C are allowed. Hot treatment should not be performed when foods are in containers.

- **Latin America**

SKYGREEN® PETG S2008 meets the requirements of MERCOSUR food contact regulation. SKYGREEN® PETG S2008 products are produced from monomers and additives listed in accordance with MERCOSUR's Positive List(GMC/RES. N°02/12 and GMC/RES. N°32/07).

- **NSF/ANSI Standard 51 Food Equipment Materials**

SKYGREEN® PETG S2008 product is certified to NSF/ANSI Standard 51. A list of certified grades and detailed information can be found at :

<http://info.nsf.org/Certified/Food/Listings.asp?Company=C0092244&Standard=051>

### 4. Medical Regulations

- **Drug Master File (DMF No)**

SK Chemicals' PETG resin, designated as SKYGREEN® PETG S2008, has DMF 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/DrugMasterFiles/DMFs/default.htm>

- **ISO 10993 & USP Class VI**

SK Chemicals' PETG resin, designated as SKYGREEN® PETG S2008, complies with ISO 10993 guidelines. (List of Testing Performed on SKYGREEN® PETG S2008 : 10993-3 Genotoxicity, 10993-4 Hemocompatibility, 10993-5 Cytotoxicity, 10993-6 Muscle Implantation, 10993-10 Sensitization/Irritation/Intracutaneous, 10993-11 Acute Systemic Toxicity/Sub Chronic Systemic Toxicity, USP <661> USP Physiochemical for Plastics and USP <381> Elastomeric Closures for Injection)The testing of the material has shown that SKYGREEN® PETG S2008 is safe for use in medical device packaging for terminal sterilization and has met USP Class VI certification.

- **ISO 11607-1: 2019**

SKYGREEN® PETG S2008 is meet the testing requirements as defined in ISO 11607-1: 2019, as it applies to raw material and not the finished device.

- **USP <661>**

SKYGREEN® PETG S2008 complies with the compositional requirements and specifications of USP <661> Containers – Plastics.

## 5. European Regulations

- **94/62/EC on packaging and packaging waste**

Heavy metals, specifically lead (Pb), cadmium (Cd), mercury (Hg) and hexavalent chromium (Cr(VI)), were not detected within the detection limit (<1.0 mg/kg). In fact, none of the above heavy metals are used in manufacturing or formulating SKYGREEN® PETG S2008 resin. Therefore, it can safely be concluded that SKYGREEN® PETG S2008 is in accordance with European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste.

- **EN 71-3: 2013 Safety of Toys (Migration of Certain Elements)**

All of the elements listed in EN 71-3: 2013 were not detected within the detection limit (<1.0 mg/kg). Also, they are not used to manufacture or formulate SKYGREEN® PETG S2008 resin. Therefore, it can safely be concluded that SKYGREEN® PETG S2008 is in accordance with EN 71-3: 2013 Safety of Toys (Migration of Certain Elements).

- **2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast, Directive 2002/95/EC repealed 3 January 2013)**

Lead (Pb), cadmium (Cd), mercury (Hg), chromium VI (Cr(VI)), polybrominated biphenyl (PBB), and polybrominated diphenyl ethers (PBDE) were not detected within the detection limit (<1.0 mg/kg). Also, they are not used to manufacture or formulate SKYGREEN® PETG S2008 resin. Therefore, it can safely be concluded that SKYGREEN® PETG S2008 is in accordance with 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

- **ANNEX II LIST OF SUBSTANCES PROHIBITED IN COSMETIC PRODUCTS and ANNEX III LIST OF SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS LAID DOWN of EC No 1223/2009**

SK chemicals do not add any of the substances listed in the Annex II of EC No 1223/2009 in manufacturing process of SKYGREEN® PETG S2008 resin. And SKYGREEN® PETG S2008 does not contain any preservative substances, including the list of preservatives allowed in ANNEX V LIST OF PRESERVATIVES ALLOWED IN COSMETIC PRODUCTS of EC 1223/2009.

- **Regulation (EC) No 999/2001 of the European Parliament and of the Council : Prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in animals**

SK chemicals, do not add the any substances of animal derived materials in manufacturing process of SKYGREEN® PETG S2008 resin.

- **Regulation (EC) No. 1005/2009 on Substances that Deplete the Ozone Layer; 40 CFR Part 82 Subpart E, ODS**

SKYGREEN® PETG S2008 does not contain and are not manufactured with, any ozone depleting chemicals in accordance with Appendix A and B of 40 CFR Part 82. (Class I & II controlled substances)

\* Ozone depleting chemicals are those substances which deplete the ozone layer and are widely used in refrigerators, airconditioners, fire extinguishers, in dry cleaning, as solvents for cleaning, electronic equipment and as agricultural fumigants.

Ozone depleting chemicals controlled by Montreal Protocol include:

- Chlorofluorocarbons (CFCs)
  - Halon
  - Carbon tetrachloride (CCl<sub>4</sub>), Methyl chloroform (CH<sub>3</sub>CCl<sub>3</sub>)
  - Hydrobromofluorocarbons (HBFCs)
  - Hydrochlorofluorocarbons (HCFCs)
  - Methyl bromide (CH<sub>3</sub>Br)
  - Bromochloromethane (CH<sub>2</sub>BrCl)
- **Regulation (EU) 2019/1021 on persistent organic pollutants (POPs)**  
 SKYGREEN<sup>®</sup> PETG S2008 does not contain any Persistent Organic Pollutants (POP) in annex I, II, III, IV of REGULATION (EU) 2019/1021 the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants(recast).
  - **Regulation (EU) No. 528/2012 on Biocidal Products (repealed and replaced Directive 98/8/EC)**  
 Any biocidal products are not intentionally employed in SKYGREEN<sup>®</sup> PETG S2008.
  - **Directive 2005/84/EC, Commission Decision 1999/815/EC (Phthalates), as amended; Consumer Product Safety Improvement Act of 2008**  
 SKYGREEN<sup>®</sup> PETG S2008 does not contain following phthalates in accordance with EU Phthalate Directives.

Phthalates	CAS Nos	EINECS Nos	Restrictions
bis (2-ethylhexyl) phthalate (DEHP)	117-81-7	204-211-0	0.1 % by mass of the plasticized material in toys and childcare articles
dibutyl phthalate (DBP)	84-74-2	201-557-4	
benzyl butyl phthalate (BBP)	85-68-7	201-622-7	
di-"isononyl" phthalate (DINP)	28553-12-0 68515-48-0	249-079-5 271-090-9	0.1 % by mass of the plasticized material in toys and childcare articles which can be placed in the mouth by children
di-"isodecyl" phthalate (DIDP)	26761-40-0 68515-49-1	247-977-1 271-091-4	
dioctyl phthalate (DNOP)	117-84-0	204-214-7	

## 6. US Regulations

- **CONEG (Coalition of Northeastern Governors)**  
 Heavy metals and heavy metal compounds of lead (Pb), mercury (Hg), cadmium (Cd) and hexavalent chromium (Cr(VI)), are not intentionally employed in SKYGREEN<sup>®</sup> PETG S2008. Incidental amounts, if present, are below 100 ppm, the threshold limit set forth by the CONEG requirements.
- **California Proposition 65**  
 SK Chemicals' SKYGREEN<sup>®</sup> PETG S2008 is in accordance with the latest version (announced January 23, 2020) of California Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986. SKYGREEN<sup>®</sup> PETG S2008 does not require a warning about chemicals known cancer causing or reproductive toxicity chemicals in California Proposition 65.
- **US Nuclear Regulatory Commission Title 10 CFR part 20**  
 Based on our current knowledge of the raw materials and manufacturing process of SKYGREEN<sup>®</sup> PETG S2008, we have no reason to expect that this product contains any radioactive substances. (Relevant Regulation: Title 10 CFR part 20 of the US

## 7. Others

- **Bisphenols**

SKYGREEN® PETG S2008 does not contain Bisphenols (A, AP, AF, B, BP, C, C 2, E, F, G, M, S, P, PH, TMC, Z).

- **Halogens**

SK chemicals, do not add the following substances in manufacturing process of SKYGREEN® PETG S2008. Therefore, our product is free of halogens (In the modern IUPAC nomenclature, these are known as group 17).

- Fluorine (F)
- Chlorine (Cl)
- Bromine (Br)
- Iodine (I)
- Astatine (At)

- **Polycyclic aromatic hydrocarbons (PAHs)**

SK chemicals, do not add the following substances in manufacturing process of SKYGREEN® PETG S2008.

- 1,2-dihydro-acenaphthene; (CAS# 83-32-9)
- 9H-Fluorene; (CAS# 86-73-7)
- Acenaphthylene; (CAS# 208-96-8);
- Anthracene; (CAS# 120-12-7)
- Benz(a)anthracene; (CAS# 56-55-3)
- Benzo(a)pyrene; (CAS# 50-32-8)
- Benzo(b)fluoranthene; (CAS# 205-99-2)
- Benzo(e)pyrene; (CAS# 192-97-2)
- Benzo(ghi)perylene; (CAS# 191-24-2)
- Benzo(j)fluoranthene; (CAS# 205-82-3)
- Benzo(k)fluoranthene; (CAS# 207-08-9)
- Chrysene; (CAS# 218-01-9)
- Dibenz(a,h)anthracene; (CAS# 53-70-3)
- Fluoranthene; (CAS# 206-44-0)
- Indeno(1,2,3-cd)pyrene; (CAS# 193-39-5)
- Naphthalene; (CAS# 91-20-3)
- Phenanthrene; (CAS# 85-01-8)
- Pyrene; (CAS# 129-00-0)

- **Latex content**

SKYGREEN® PETG S2008 does not contain natural rubber latex or dry natural rubber.

- **Transmissible Spongiform Encephalopathy (TSE)/ Bovine Spongiform Encephalopathy (BSE)**

SKYGREEN® PETG S2008 does not contain any substances (Substances of Animal Origin Regulation EC 999/2001, as amended; 21 CFR 189.5; 21 CFR 700.27) of animal derived materials.

- **Food Allergens**

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SKYGREEN<sup>®</sup> PETG S2008 is not formulated to contain the major food allergens or essential proteins derived there from. (The major food allergens include eggs, fish, milk, peanuts, shellfish, soy beans, tree nuts, and wheat).

- **Butylated Hydroxytoluene (BHT) and Phthalates**  
SK chemicals, do not add the BHT and any Phthalates in manufacturing process of SKYGREEN<sup>®</sup> PETG S2008.
- **Conflict Minerals**  
Any 3TG (Tantalum, Tin, Gold, Tungsten) are not intentionally employed in SKYGREEN<sup>®</sup> PETG S2008.
- **Mineral oil saturated hydrocarbons(MOSH) and mineral oil aromatic hydrocarbons(MOAH).**  
Based on our current knowledge of the raw materials and manufacturing process of SKYGREEN<sup>®</sup> PETG S2008, we have no reason to expect that this product contains MOSH and MOAH.  
(for further information see : <https://www.produktqualitaet.com/en/food/contaminants/mineral-oil-hydrocarbons-mosh-moah.html>)
- **Optical brighteners and fluorescent agents.**  
We, SK Chemicals, do not add Optical brighteners, optical brightening agents (OBAs), fluorescent brightening agents (FBAs) and fluorescent whitening agents (FWAs) (such as 4,4-diamino-2,2-stilbenedisulfonic acid and 4 4'-bis(benzoxazolyl)-cis-stilbene and 2 5-bis(benzoxazol-2-yl)thiophene) in manufacturing process of SKYGREEN<sup>®</sup> PETG S2008.
- **Dioxin.**  
Based on our current knowledge of the raw materials and manufacturing process of SKYGREEN<sup>®</sup> PETG S2008, we have no reason to expect that this product contains 1,4-Dioxin, polychlorinated dibenzodioxin(PCDD) and its isomers.
- **Zero Discharge of Hazardous Chemicals Manufacturing Restricted Substances List (ZDHC MRSL)**  
SKYGREEN<sup>®</sup> PETG S2008 does not contain any substances listed in the ZDHC MRSL Version 1.1.  
Which can be seen at:  
<https://www.roadmaptozero.com/fileadmin/layout/media/downloads/en/MRSL.pdf>

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