SPL LIFE SCIENCES
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Tel: +82-31-533-4800 | Fax: +82-31-533-1430

Regulatory Compliance Statement

Base on the authorized confirmation from resin manufacturer,
SPL Life Science Co., Ltd declare that resin used for our products does not contain any substances restricted by the regulations listed below.

- **RoHS III**_EU Directive 2015/863, updated Jul 22, 2021
- **REACH SVHC**_Regulation (EC) 1907/2006, updated Feb 04, 2026
- **CA Prop65**, updated Dec 08, 2025
- **TSCA(Toxic Substances Control Act)**, updated Jul 20, 2025
- **Phthalate**_ Regulation (EU) 10/2011, updated Jul 12, 2023
- **PFAS**
  -EU POPs & PFAS _Regulation (EU) 2019/1021, updated Oct 15, 2025
  -TSCA Section8(a)(7)_EPA PFAS Substances list, updated Nov 13, 2025

▶Items : **Conical Tubes**

#50015 / 51015 / 50050 / 50515 / 50250 / 50040

#50115 / 51115 / 50150 / 51150

#54015 / 54115 / 54050 / 54150

Very Truly Yours,

SPL Life Sciences Co., Ltd.

DOMINIQUE DUTSCHER SAS

Jun 29, 2026
MK. Kim
QC Manager
SPL Life Sciences Co., Ltd.

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Letter of Conformity

This letter hereby certifies that the below listed SPL's product meets all established SPL's product specifications as described below in accordance with ISO 9001:2015 & ISO 13485:2016 Quality Management System.

SPL Conical tubes are made of virgin PP & HDPE, sterilized to an SAL of 10^{-6} by irradiation according to ISO 11137 guidelines, non-pyrogenic according to the result based on LAL test described in USP<85>, non-cytotoxic according to the test result based on ISO 10993-5 standard and possibly used in a clean room environment.

SPL Conical tubes complies with the requirements of the EU PPWR_Regulation (EU) 2025/40, specifically ensuring that the total concentration of lead (Pb), cadmium (Cd), mercury (Hg), and hexavalent chromium (Cr VI) does not exceed 100mg/kg (100ppm)

Based on the information obtained from our suppliers, any of raw materials used to manufacture the product is the synthetic material and the substances below are not used or contacted in the manufacturing process.

1) Substances regulated by RoHS3(update_2019.07.22) & REACH SVHC(update_2026.02.04)
2) ADC_TSE/BSE(bovine, ovine, caprine)
3) GMO
4) Gluten
5) Melamine
6) Allergens(soybean, wheat, tree nut, peanut, fish, milk, egg and shellfish)
7) ICH Q3C R8(Residual solvents)
8) Metal catalyst & Metal reagent
9) Natural rubber
10) Latex
11) Aflatoxins
12) ICH Q3D Elemental Impurities(Table 5.1)
13) Nitrosamines(NDMA, NEIPA, NDIPA, NDBA, NMBA)
14) Additive(slip agent)
15) PVC, Silicone oil and Lipid
16) PFAS
    -EU POPs & PFAS _Regulation (EU) 2019/1021(update_2025.10.15)
    -TSCA Section8(a)(7)_EPA PFAS Substances list(update_2015.11.13)

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▶Items : Conical tube

#50015 / 51015 / 50050 / 50515 / 50250 / 50040

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Very Truly Yours,
SPL Life Sciences Co., Ltd.



Jul 01, 2026
MK. Kim
QC Manager
SPL Life Sciences Co., Ltd.

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