SCHOTT TopLyo® Vials

Physical & Chemical Properties
The ultra thin layer of SCHOTT TopLyo® vials is characterized by the following properties:

<table>
<thead>
<tr>
<th>Physical Data</th>
<th>Chemical Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Layer thickness of ~40 nm</td>
<td>Chemical layer properties: Si-O-C-H</td>
</tr>
<tr>
<td>Stable against mechanical load</td>
<td>Long-term stable layer system during storage proven by accelerated aging at 40 °C and room temperature after 3 years</td>
</tr>
<tr>
<td>Stable washing process</td>
<td>Bond covalently to the material and chemically uniform</td>
</tr>
</tbody>
</table>
| Stable sterilization:  
- Autoclaving (121 °C)  
- Depyrogenation (dry heat treatment at 250 °C – 350 °C) | Dense coating (i.e. non porous) |
| Contact angle for water: ~100 ° (hydrophobic surface) |

Verifications
Contact angles measured over 36 months at room temperature

Method:
- 1400 SCHOTT TopLyo® vials, 2R  
- WFI, phosphate and citrate buffer (pH 5, 7, 8)  
- Sterilization at 121 °C, 30 min  
- Samples stored at 40 °C

Result:
- Contact angle > 90°

Improved lyo cake aesthetics

Method:
- 10 R vials Type I glass & SCHOTT TopLyo® vials  
- 5.0 ml formulation dried in 10 R vials with different surfaces  
- 0.15 mg/ml human growth hormone, 40 mg/ml mannitol and 10 mg/ml sucrose  
- Phosphate/glycine buffer (pH 7.0)  
- Sterilization using 0.2 μm PES Filter, 25 °C, 30 min

Result:
- Less disruption in SCHOTT TopLyo® vials  
- Less dry material pulling from the edge with SCHOTT TopLyo®
Product Information
Thanks to our patented coating technology, vials are endowed with a stable and covalently bond hydrophobic interior.

Value-adding Product Benefits and Services
Application ranges

**Improved lyo cake**
Less disruption and production losses due to reduced climbing at vial edges

**Optimized yield**
Reduced adsorption at the inner glass surface minimizes the residual volume after reconstitution

**Dimensional changes not required**
Due to the very thin coating layer (~40 nm), no dimensional changes are needed

**Fogging**
Reduction of surfactant driven Marangoni flow

Maximum inspection – validated process

| Stage 1 | Two 100% on-site inspections on each reactor (temperature, optical plasma emission) |
| Stage 2 | Control of process parameters (on-line, including gas flow, vacuum, microwaves) |
| Stage 3 | Automatic System Monitoring of long-term stability (maintenance, calibration of the actuators and sensor, data acquisition and long term storage) |

Packaging
- SCHOTT TopLyo® vials are delivered in special trays with optional separators to avoid glass-to-glass contact
- A standard Euro Pallet (1200 x 800 mm) contains 15–27 layers of 9 trays each

<table>
<thead>
<tr>
<th>Capacity</th>
<th>2 R</th>
<th>6 R</th>
<th>8 R</th>
<th>10 R</th>
<th>15 R</th>
<th>20 R</th>
<th>50 R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pieces/ tray</td>
<td>344</td>
<td>186</td>
<td>186</td>
<td>154</td>
<td>154</td>
<td>99</td>
<td>51</td>
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</tbody>
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