SCHOTT Type I plus® Vials

General Product Information
SCHOTT Type I plus® vials consist of SCHOTT Type I glass combined with the purity and inertness of a quartz-like inner surface (100% SiO₂ coating). They comply with all current standards, such as Ph. Eur., USP and JP.

Due to the excellent properties of the layer, this product can be used in highly specific application ranges, especially biopharmaceuticals. Unlike ammoniumsulfate treatment or baked-on silicone, the SiO₂-layer has a high barrier improvement factor against ion leaching and thereby minimizes drug container interaction. SCHOTT specifies a limit value of 0.17 μg/ml Na after 6h autoclaving at 121 °C with 0.1 M HCl for all sizes.

Physical & Chemical Product Properties
The layer of SCHOTT Type I plus® vials is characterized by the following properties:

### Physical Data
- Layer thickness of approx. 100 – 200 nm
- Stable against mechanical load
- Stable washing process
- Stable sterilization:
  - Autoclaving (121 °C)
  - Depyrogenation (dry heat treatment at 250 °C – 350 °C)

### Chemical Data
- Chemical layer properties: SiO₂
- Long-term stable layer system during storage proven by accelerated aging at 40 °C
- Pure silica surface bond covalently to the material and chemically uniform
- Dense coating (non porous)
- Surface shows excellent barrier properties in avoiding ion leaching: Sodium, Calcium, Boron, Silicon and Aluminium

### Verifications
#### Stability
**Method:**
- 10 R vials produced in 2002 and vials produced in 2012
- Long term sodium leaching after 6 hours initial autoclaving
- 0.1 M HCl at 121 °C
**Result:**
- SiO₂ of SCHOTT Type I plus® layer stable for more than 10 years

**Reduction of ion exchange**
**Method:**
- 1h autoclaving 0.4 M HCl at 121 °C
- Leached ions in μg/ml by AAS
**Result:**
- Diffusion barrier effective for all other elements of the glass matrix
- All metallic ions are suppressed to a level below their respective detection limit

### SCHOTT Improvement
<table>
<thead>
<tr>
<th>Type I vials</th>
<th>SCHOTT Type I plus®</th>
<th>Improvement Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium (Na⁺)</td>
<td>3.5</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Calcium (Ca²⁺)</td>
<td>1.1</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>Boron (B₃⁺)</td>
<td>3.5</td>
<td>&lt; 0.10</td>
</tr>
<tr>
<td>Silicon (Si₄⁺)</td>
<td>5.0</td>
<td>&lt; 0.30</td>
</tr>
<tr>
<td>Aluminium (Al₃⁺)</td>
<td>2.3</td>
<td>&lt; 0.05</td>
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Product Information
Thanks to our patented coating technology, a very high barrier improvement factor against ion leaching is achieved.

Value-adding Benefits and Services
Application ranges

<table>
<thead>
<tr>
<th>Verified barrier</th>
<th>Radioactive diagnostics</th>
<th>Enzymes &amp; sensitive formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barrier layer prevents depletion of glass container by drug formulation</td>
<td>Reduction of residual radioactivity due to less adsorption of radioactive molecules</td>
<td>Reactivity of enzymes and formulations is unaffected as no metal ion can be solved out of the glass</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Proteins</th>
<th>Highly pure substances</th>
<th>WFI &amp; alkali sensitive products</th>
</tr>
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<tbody>
<tr>
<td>Show reduced adsorption on the inner glass surface</td>
<td>Are preserved even at long stocking periods, as the quartz-like coating is chemically inert</td>
<td>Unbuffered reagents, e.g. water for injection, are better protected against shifts in pH</td>
</tr>
</tbody>
</table>

Packaging

- SCHOTT Type I plus® 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>4 R</th>
<th>6 R</th>
<th>8 R</th>
<th>10 R</th>
<th>15 R</th>
<th>20 R</th>
<th>30 R</th>
<th>50 R</th>
<th>100 R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pieces / tray</td>
<td>344</td>
<td>344</td>
<td>186</td>
<td>186</td>
<td>154</td>
<td>154</td>
<td>99</td>
<td>99</td>
<td>51</td>
<td>35</td>
</tr>
</tbody>
</table>

Maximum inspection – validated process

Stage 1
Two 100% in situ 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)

All specifications are subject to change without prior notice.

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