

# SCHOTT Type I plus<sup>®</sup> Vials



## General Product Information

SCHOTT Type I plus<sup>®</sup> vials consist of SCHOTT Type I glass combined with the purity and inertness of a quartz-like inner surface (100% SiO<sub>2</sub> 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 bio-pharmaceuticals. Unlike ammoniumsulfate treatment or baked-on silicone, the SiO<sub>2</sub>-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<sup>®</sup> 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: <ul style="list-style-type: none"> <li>· Autoclaving (121 °C)</li> <li>· Depyrogenation (dry heat treatment at 250 °C – 350 °C)</li> </ul>

Chemical Data
Chemical layer properties: SiO <sub>2</sub>
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

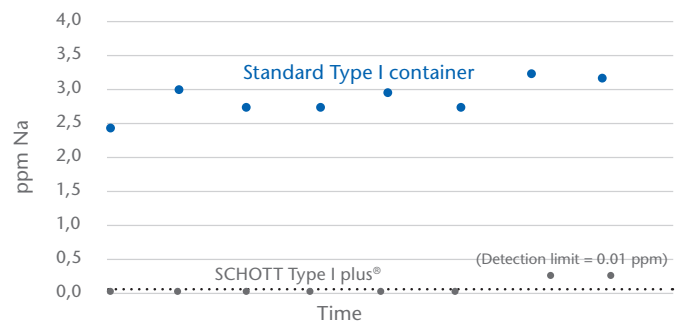
### Stability

#### 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:

- SiO<sub>2</sub> of SCHOTT Type I plus<sup>®</sup> 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:

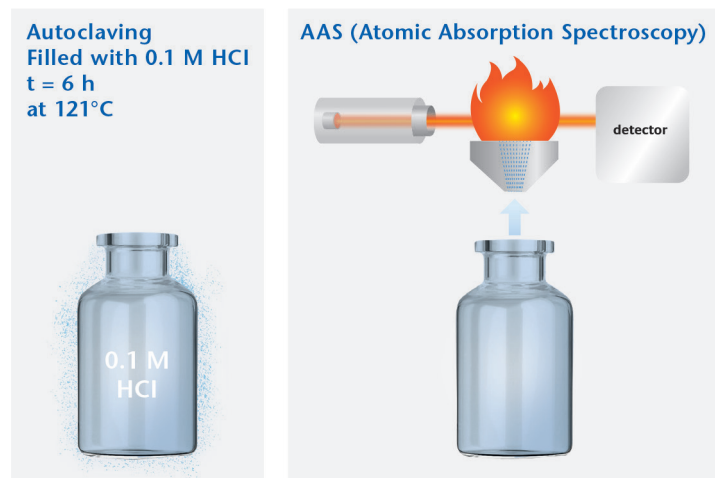
- Diffusion barrier effective for all other elements of the glass matrix
- All metallic ions are suppressed to a level below their respective detection limit

	Type I vials	SCHOTT Type I plus <sup>®</sup>	Improvement Factor
Sodium (Na <sup>+</sup> )	3.5	< 0.01	> 350
Calcium (Ca <sup>2+</sup> )	1.1	< 0.05	> 22
Boron (B <sup>3+</sup> )	3.5	< 0.10	> 35
Silicon (Si <sup>4+</sup> )	5.0	< 0.30	> 15
Aluminium (Al <sup>3+</sup> )	2.3	< 0.05	> 45



## Product Information

Thanks to our patented coating technology, a very high barrier improvement factor against ion leaching is achieved.



## 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)

## Value-adding Benefits and Services

### Application ranges

#### Verified barrier

Barrier layer prevents depletion of glass container by drug formulation

#### Radioactive diagnostics

Reduction of residual radioactivity due to less adsorption of radioactive molecules

#### Enzymes & sensitive formulation

Reactivity of enzymes and formulations is unaffected as no metal ion can be solved out of the glass

#### Proteins

Show reduced adsorption on the inner glass surface

#### Highly pure substances

Are preserved even at long stocking periods, as the quartz-like coating is chemically inert

#### WFI & alcali sensitive products

Unbuffered reagents, e.g. water for injection, are better protected against shifts in pH

## 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

Capacity	2 R	4 R	6 R	8 R	10 R	15 R	20 R	30 R	50 R	100 R
Pieces / tray	344	344	186	186	154	154	99	99	51	35