

## MINI desiccant bags

**TROPACK Packmittel GmbH manufacture these bags.**

### Bag material

They are made from hot-sealed DuPont Tyvek® - a highly durable material consisting of spun polyolefin fibres, used by pharma for decades. The tightly interwoven fibres guarantee a 100% dust-proof product, while the surface of the Tyvek® desiccant bags is extremely wear-resistant and lint-free. The standard printing on the bags comply with European Union regulations (Regulation EC No. 450/2009) and contains the warning “Do not eat” in German, English, French and Spanish.



### Packaging

MINI desiccant bags come in basic packets printed with usage instructions. These packets consist of polyethylene bags, and comply with the requirements established in DIN 55473 regarding protection against water vapour. The extra packaging used for shipment consists of a resealable metal bucket with low water-vapour permeability, thus ensuring a long shelf life. The MINI desiccant bags are also available in cardboard boxes.

### Shelf life

MINI desiccant bags may be stored in a dry place at room temperature for extended periods of time without losing their effectiveness. Every basic packet contains a moisture indicator for visual checks.

Shelf life in sealed packets:

- Standard (in a metal bucket) – up to 24 months
- In a cardboard box (optional) – 6-9 months

### Desiccants

Standard MINI desiccant bags contain silica gel/white gel or a molecular sieve as the desiccant:

- **Silica gel** provides reliable protection for the tiniest of packaging thanks to its high adsorption capacity at higher relative humidity (over 50% RH)
- **Molecular sieves** are commonly used as desiccants in lower relative humidity (under 50% RH) and at lower temperatures, e.g. cold chains. A 4Å molecular sieve is used as a standard, 3Å, 5Å and 10Å/13X can also be used tailored to the required purpose

The desiccants are chemically neutral, and provide reliable protection against mould and rust.

## Compliance: FDA & EU for pharmaceuticals, food and diagnostics

These MINI desiccant bags comply with requirements regarding contact with food. Some products in the MINI desiccant bag range are registered with the FDA in a DMF (Drug Master File Type III).

**Desiccants:** The white-gel and molecular-sieve desiccants comply with

- The requirements of the US FDA (Food & Drug Administration) regarding contact with food (incl. **21 CFR** 174.5, 177.200, 182.1711).
- European Union requirements regarding contact with food (incl. Regulation (EC) No. 1935/2004).

**Tyvek® bag material:** Tyvek®, as the bag material for the MINI desiccant bags, complies with

- FDA** regulatory requirements for polyolefins (**21 CFR** 177.1520) and additives (21 CFR 178.2010).
- European Union** requirements established in Regulation (**EC**) No. **1935/2004** regarding contact with food.

**Printing ink:** The ink used to print on our MINI desiccant bags

- Complies with the requirements of the US FDA (21 CFR 73, 74 Subpart A, ...), and is registered with the **FDA** in a DMF (Drug Master File Type IV).

## Weight and Dimensions

Custom weight and dimension can be offered for larger quantities, but there are some limitations on the dimensions that can be produced in the machines that are used.

Standard weight and dimensions are:

Fill weight	0.5 gram	0.5 gram	1.0 gram	1.0 gram	1.5 gram
Dimensions	16x27 mm	20x30 mm	20x40 mm	23x32 mm	20x40 mm
Bag (PE)	1.000	1.000	1.000	1.000	1.000
Metal bucket	5.000	5.000	5.000	5.000	5.000
Box	10.000	10.000	10.000	10.000	10.000

Fill weight	2.0 gram	2.5 gram	3.0 gram	3.5 gram	4.0 gram	5.0 gram
Dimensions	23x50 mm	23x58 mm	23x58 mm	23x58 mm	23x65 mm	23x70 mm
Bag (PE)	500	500	500	500	250	200
Metal bucket	2.500	2.500	2.000	2.000	2.000	1.000
Box	5.000	5.000	4.000	4.000	3.000	2.000