

ACRYLICS FOR ORTHODONTIC APPLIANCES

Tests on the biocompatibility of

The biological evaluation of the Orthocryl® assortment acc. to DIN EN ISO 10993-1 is based on following actions:

- Cytotoxicity tests acc. to DIN EN ISO 10993-5
The materials do not show any cytotoxic effects.
- Chemical analyses of eluted components acc. to DIN EN ISO 10993-12
The amount of extractables is below scientifically acknowledged thresholds.
- Test for the irritating effect to the mucosa (HET-CAM Test)
No irritant properties for the mucosa were detected.
- Test for mutagenicity (Ames test)
No genetic mutations were detected.

Conclusion Orthocryl®:

In the above-mentioned tests, Orthocryl® displayed no properties that were toxic, irritating to the mucosa or mutagenic.

Tests on the biocompatibility of

Orthocryl® LC does not contain methyl methacrylate, dibenzoyl peroxide or bisphenol-A and is therefore an anti-allergenic and environmentally friendly alternative to conventional self(cold)-curing acrylic for orthodontic appliances. Furthermore, the vapor pressure is very low for the monomers in use and thus the dental technician is subjected to much lower levels of odor pollution.

The biological evaluation of the Orthocryl® LC assortment acc. to DIN EN ISO 10993-1 is based on following actions:

- Cytotoxicity tests acc. to DIN EN ISO 10993-5
The materials do not show any cytotoxic effects.
- Chemical analyses of eluted components acc. to DIN EN ISO 10993-12
The amount of extractables is below scientifically acknowledged thresholds.

Conclusion Orthocryl® LC:

In the above-mentioned tests, Orthocryl® LC displayed no properties that were toxic, irritating to the mucosa or mutagenic.

General information:

All acrylic components were tested in polymerized form, which is the form used for patients.

The tests were carried out by accredited laboratories with non-animal testing procedures.

All Orthocryl®/Orthocryl® LC products are approved as medical devices for long-term use in the mouth (> 30 days).