

Acrylics for orthodontic appliances

Tests on the biocompatibility of



The following test procedures were used to determine the biocompatibility of Orthocryl® in all colors and forms of presentation:

- Test for cytotoxicity (DIN EN ISO 10993-5)
The test serves to evaluate the proliferation of the connective tissue cells L-929.
- Test for the irritating effect to the mucosa (HET-CAM Test)
The so-called HET-CAM test was used to determine irritant properties for the mucosa.
- Test for mutagenicity (Ames test)
The Ames test is a screening test employed worldwide that uses bacterial strains to test for genetic mutations.

The tests were carried out by K. U. Schendel, L. Erdinger, G. Komposch, H.-G. Sonntag, Polyclinic for orthodontics and the department for hygiene and medical microbiology at Heidelberg University Hospital.

The tests are recognized by official bodies (DIN EN ISO, BfR, MDC) for the testing of medical products with non-animal testing procedures.

The acrylic was tested in polymerized form, which is the form used for patients.

Conclusion:

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

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Orthocryl® LC does not contain methyl methacrylate, or dibenzoyl peroxide or bisphenol-A and is therefore an anti-allergenic and environmentally friendly alternative to conventional self(cold)-curing acrylic for orthodontic appliances.

The accredited test laboratory MDS (www.mdsservices.de) submitted Orthocryl® LC to the following toxicological tests:

- A cytotoxicity test acc. to DIN EN ISO 10993-5 (elution time 7d).
- A chemical analysis of eluted components acc. to DIN EN ISO 10993-12.
- A biological evaluation of existing documents and results acc. to DIN EN ISO 10993-1.

Since the vapor pressure is very low for the monomers in use, the dental technician is subjected to much lower levels of odor pollution.

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