CERTIFICATE

Certificate of quality

Acrylics for orthodontic appliances – biocompatibility tests

Five versions of neon-colored acrylics with the brand name Orthocryl® from Dentaurum:

neon orange, neon blue, neon yellow, neon green, neon pink

and seven other types of Orthocryl® were tested for biocompatibility using different procedures. The procedures were used for testing

- cytotoxicity
- mucosal irritation
- mutagenicity

Three in vitro test procedures were used, which

1. are scientifically recognized and recommended by official bodies such as DIN (German Standards Institute) or the BGA (Federal Health Agency)
2. were carried out without testing on animals.

The acrylics were tested in the polymerized state, which is how they are used with patients. In tests B and C trimmed material was also tested.

Test A

In this test none of the color versions of Orthocryl® tested exhibited toxic potential

Cytotoxicity was tested according to DIN guidelines using the agar overlay test, in which the specimens are placed on specific cells in a cell culture (method refer also to Schendel et al., Fortschr. Kieferorthop. 53 (1992), 263-272, No. 5).

Test B

In this test none of the color versions of Orthocryl® tested exhibited mucosal irritation potential

Mucosal irritation potential was tested using the HET-CAM test on the blood vessels of incubated eggs (method refer also to Schendel et al., Fortschr. Kieferorthop., 1994).

Test C

In this test none of the color versions of Orthocryl® tested exhibited mutagenic potential

Mutagenicity potential was tested using the Ames test (a test for gene mutation on specific bacterial strains). The Ames test is the most commonly used screening test in the world for testing gene mutation (method refer also to Ames et al., Mutat. Res. 31 (1975), 347-346).

Summary: In the tests cited above the polymerized neon-colored acrylics and seven other versions of Orthocryl® exhibited no:

toxic, mucosal irritation or mutagenic potential.

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