Aligner material information

clearcorrect
A Straumann Group Brand

OVERVIEW

This sheet is meant to provide information to dental practitioners about the raw material used to manufacture ClearCorrect aligners and retainers. If you have questions about something you don't see covered here, contact us at (888) 331-3323. We have real-live representatives ready to help. All ClearCorrect products are proudly made in the USA.

BACKGROUND AND DEVELOPMENT

Formulating the material for an orthodontic appliance involves achieving a balance between material elasticity and force exertion. This is actually very important because if the material is too flimsy, teeth will not move. If it is too rigid, there can be a lot of sudden force (and pain). Teeth are not all that easy to move and the material is actually under quite a bit of pressure when seated. As with any polymer (plastic) under stress, the material loses its elasticity slowly with time. As a result, aligners lose their original efficacy, causing slower results or requiring replacements.

Patient compliance plays an important role in clear aligner therapy. If the aligners exert too much pressure on the teeth, the resulting discomfort may discourage patients from wearing their aligners for the prescribed amount of time—thus adding time and cost to treatment. In order to optimize compliance, aligners should retain flexibility while exerting continuous gentle force.

ClearCorrect aligners are manufactured using a unique material that provides an excellent balance between force and elasticity. The slight, gradual pressure exerted by the aligners is sufficient for effective orthodontic results without unnecessary patient discomfort. Our products are made from a proprietary polymer that has the mechanical properties of an engineered and functional resin while maintaining optical clarity, stress relaxation and desirable biocompatibility properties for an oral appliance.

From the outset of the development phase of this new material, an attempt was made to establish these ideal characteristics for an orthodontic aligner. The result is an industry innovation. The material was formulated to achieve an exact degree of elasticity while retaining the stain-resistance and biocompatibility standards we were simply not willing to compromise on. The final production material was tested in simulated chemical and biological environments and then the real fun began—doctor and patient feedback confirmed that the final material not only met but exceeded our original expectations.

FDA INFORMATION

Proprietary Name: ClearCorrect

Classification Name: Aligner, Sequential

Product Code: NXC

Device Class: 2

Regulation Number: 872.5470

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RAW MATERIAL PROPERTIES

Appearance:	thin, rigid semi-transparent sheet
Odor:	n/a
Physical state:	solid
pH:	n/a
Vapor pressure:	n/a
Boiling point:	n/a
Melting point:	n/a
Solubility in water:	negligible
Specific gravity:	1.203

CHEMICAL COMPOSITON

Chemical class: polyurethane
CAS#: 137873-51-9
Notes: Bisphenol-A (“BPA”) and phthalate free. No product ingredients greater than 0.1% are listed by OSHA, NTP or IARC as suspect carcinogens.

STABILITY/REACTIVITY

Room temperature:	stable
Conditions to avoid:	do not heat above 100° C (212° F) unless contained.
Incompatibility:	none
Decomposition products:	may emit CO, CO2 and organic fumes if combusted.
Hazardous polymerization:	will not occur

TOXICOLOGICAL INFORMATION

This product has undergone biocompatibility testing according to U.S. Pharmacopeia XXII, Part 88, Class VI guidelines.

TSCA STATUS

The EPA (Environmental Protection Agency) adds chemicals to the TSCA inventory (Toxic Substances Control Act) following EPA's receipt of an official notice signaling the manufacturer's intent to produce a chemical substance that the EPA has previously reviewed and approved. This product is a mixture of ingredients and all of them are listed in the TSCA inventory.

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SARA RATINGS

Safety Analysis and Risk Assessment, Title III, Section 311):

Fire hazard:	no
Reactive hazard:	no
Release of pressure:	no
Acute health hazard:	no
Chronic health hazard:	no

PROPOSITION 65

No chemicals present are included in California Proposition 65 (the "Safe Drinking Water and Toxic Enforcement Act of 1986").

ECOLOGICAL/DISPOSAL INFORMATION

Incinerate or landfill waste in a properly permitted facility in accordance with federal, state, and local regulations.

TRANSPORT INFORMATION

DOT shipping name: not regulated

DOT label: n/a