Align Technology, Inc. Materials and Testing FAQs

GLOBAL CODE OF CONDUCT

Our commitment to ethical research

Align Technology, Inc. is committed to ethical research and innovation to improve orthodontic and dental treatment for communities around the globe. We support research and innovation through our own research capabilities, through sharing our knowledge and experience, and through our Research Award Program which supports clinical and scientific orthodontic and dental research. Research we fund may be basic science or clinical but, either way, we require justification that the research furthers the understanding of the field of dentistry. We review all funded research applicants to include seeking input from independent committees, and we post on our website the recipients of our grants. We also carefully review all costs associated with research we fund so costs are compliant with laws and consistent with our own policies. Whether we are conducting research or funding the research of others, we are committed to doing so ethically and in compliance with applicable law and industry standards to include filing any government required reports about our research or its funding. We appreciate that to be ethical researchers we must protect patient personal information and assure that the research is used to further legitimate dental science. We expect the researchers we fund to do the same.

Our commitment to safe and high-quality products

As a company dedicated to improving people's lives, we understand the importance of designing, manufacturing, and offering products of the highest quality, safety and predictability for our customers and their patients, employees, suppliers, and the world in which we all live. Our commitment begins with our Board of Directors, which has adopted our Global Code of Conduct, and which oversees compliance with it as well as evaluating the risks related to our business, brand and reputation. Our executive management team is responsible for identifying and assessing risks related to our business, including our products, and implementing policies and practices designed to mitigate those risks for our business as well as those using our products.

We know that to maintain the confidence of our customers and their patients, as well as to remain respected leaders in the dental industry, we need to consistently review our products and processes to meet the rigorous safety and quality standards our customers and their patients expect. Align's quality

management system ("QMS") is designed to assure we are accountable to this commitment by providing the structure, responsibilities and procedures required to achieve product safety and quality.

Align's QMS approaches quality from a global perspective since quality standards may be defined differently in each country or territory where we operate. Align's QMS is based on the highest industry standards and regulations globally and is frequently audited by third parties and regulators to assure the quality of the research, design, manufacturing, distribution and post-market surveillance of our products. To facilitate compliance with our quality controls, we document our work, keep accurate and current records and quickly investigate and resolve quality concerns. Our QMS system and our compliance with QMS prepare Align to constructively and transparently engage with our regulators to assure quality. In addition to holding ourselves accountable for the quality of our products, we have also developed operating procedures and quality agreements that allow us to hold our suppliers and distributors accountable for assuring the products and services they provide meet our stringent quality standards.

GENERAL STATEMENT

As a policy, all our products must be safe and effective for their intended uses, for our employees and those of our suppliers who help in the manufacturing process, and for the communities we serve. To achieve this requirement, we have in place policies and controls that help us govern new product development, including product design input and output, verifications and other protocols, that consider the chemicals used in our clear aligner products as well as in the manufacturing process and ultimate product disposal. Included in those protocols is a requirement that we proactively partner with suppliers to identify, replace and, if possible, eliminate chemicals of high concern with safer alternatives, when available.

We have developed a Biological Evaluation Plan which characterizes our patient contacting materials for clear aligner products based on the nature and duration of body contact, assesses the selection and materials of construction, reviews the manufacturing processes, identifies the biological endpoints of concern, evaluates any existing research data available and outlines a strategy (plan) to address areas of remaining biological risk, which may include both chemical and biological testing. Our clear aligner and retainer products have been thoroughly tested following ISO 10993-1 standard by reputable, third-party, AAALAC accredited laboratories. We produce chemical compliance reports that discuss how we comply

with material limitations or restrictions for all clear aligner product families. And, most importantly, we are committed to continually reviewing and improving our processes to make our products safer for use and the environment.

All Invisalign® aligner/retainer materials are made of medical grade, high molecular weight, thermoplastic polymers. These materials were selected for use in aligners and retainers based on their properties and safety classification and have an extensive history of use in FDA authorized products. Tests conducted to determine the biocompatibility of these materials have shown they are biocompatible and pass applicable regulatory requirements for human wear in the mouth. Based on our current knowledge and testing of the raw materials and processes used in the manufacture of aligners and retainers, we are not aware of any latex, parabens, phthalates, glutaraldehyde, per- and polyfluorinated substances (PFAS), epoxy or Bisphenol A (BPA) present in our aligners or retainers. Of course, as with any medical device, you should consult with your health professional about your aligner or retainer treatment and any applicable risks of use.

PRODUCT TESTING

Q. Do Invisalign clear aligners contain animal products? Is Invisalign treatment vegan?

A. Invisalign clear aligners do not contain animal products.

Q. Does Align Technology conduct research and development that includes animal testing?

A. No. Align does not perform research that includes animal testing. The safety and effectiveness of our medical devices relies primarily on mechanical bench and computer simulation modeling to demonstrate effectiveness. Only when global regulatory agencies require our materials demonstrate biocompatibility do we commission laboratory tests from reputable third-party laboratories. Some of these studies do involve cell-based or animal tests. Align only uses AAALAC accredited laboratories which ensures the ethical and humane use of animal models by the laboratory. (“AAALAC International”).

Q. Does Align Technology commission animal testing to other companies?

A. The safety and effectiveness of our medical devices relies primarily on mechanical bench and computer simulation modeling to demonstrate effectiveness. Only when global regulatory agencies require our materials demonstrate biocompatibility do we commission laboratory tests from reputable third-party laboratories. Some of these studies do involve cell-based or animal tests. Align only uses AAALAC accredited laboratories which ensures the ethical and humane use of animal models by the laboratory. ("AAALAC International"). AAALAC International, formerly called Association for Assessment and Accreditation of Laboratory Animal Care International, promotes the responsible treatment of animals in science through a voluntary accreditation program.

Q. If not, does Align Technology have an animal testing policy that addresses the three R's (Reduce, Replace, Refine)? Or alternatively, is Align Technology certified by an independent body, such as AAALAC?

A. As Align Technology does not perform animal testing, it is not certified by AAALAC. Align is committed to using animal-based testing only when absolutely necessary. Align is committed to using only accredited laboratories to ensure the ethical use of animal models for research including the three R's approach.

Q: Is Invisalign treatment cruelty-free?

A. There is no standard definition for cruelty free (see: https://www.ncbi.nlm.nih.gov/books/NBK24645/) Global regulatory agencies require medical device materials to demonstrate biocompatibility for their intended use. Some of these studies do involve cell-based or animal tests which are performed by an accredited third-party research company. Align only uses an AAALAC accredited laboratory that ensures the ethical and humane use of animal models by the laboratory. Align is committed to using animal-based testing only when absolutely necessary. Align is committed to using only accredited laboratories to ensure the ethical use of animal models for research.

MATERIALS

Q. Do Invisalign clear aligners contain Bisphenol-A ("BPA")?

A. All Invisalign aligner materials are made of medical grade, high molecular weight, thermoplastic polymers. These materials were selected for use in aligners and retainers based on its properties and safety classification and have an extensive history of use in FDA authorized products. Tests conducted to determine the biocompatibility of these materials show that they are biocompatible and pass applicable regulatory requirements for human wear in the mouth. Invisalign aligners are not made with latex, parabens, phthalates, glutaraldehyde, per- and polyfluorinated substances (PFAS), epoxy or Bisphenol A ("BPA"). Of course, as with any medical device, you should consult with your health professional about your aligner or retainer treatment and any applicable risks of use.

Q. Do Invisalign clear aligners and retainers contain microplastics?

A. Invisalign aligners and retainers are made from chemically and mechanically stable materials that are not prone to breakdown to microplastics when used as intended, and they do not contain microplastics as defined by the European Chemicals Agency, the U.S. National Ocean and Atmospheric Administration, and the California State Water Resources Control Board. Both the Food and Drug Administration and the Environmental Protection Agency recognize microplastics through the same definitions.

Q. How are the end products cleaned prior to packaging and shipment to the end customer?

A. Aligners, retainers, and templates go through a final cleaning process that consists of a Reverse Osmosis ("RO") purified water rinsing and Deionized water immersion. There are no cleaning agents/disinfectants used in these final steps. The final finished product has been tested to be biocompatible for use in the oral cavity.

INVISALIGN™ CLEANING CRYSTALS

Q. What is the use of this product/ material?

A. Invisalign™ Cleaning Crystals are to be diluted in water and aligners/ retainers are placed in the solution for cleaning.

Q. What are the main ingredients in the Invisalign™ Cleaning Crystals?

A. SODIUM CARBONATE, DICHLORO-1,3,5-TRIAZINETRIONE, SODIUM SALT

Q. Are the ingredients hazardous to health when used as directed?

A. The product is not hazardous to users when used as directed. Patients should be instructed to follow the dilution instructions and rinse the appliances thoroughly with tap water before inserting them into the mouth.

Q. Are there any hazards, precautions, side effects with the incorrect storage and manipulation or use of the product?

A. This product is not identified as a persistent, bio accumulative, or toxic substance.

Exposure hazard to fire: In combustion, this product emits toxic fumes. Avoid exposing the product to excessive heat and flame.

Exposure hazard to substances: When exposed to strong acids or oxidizing agents, the product liberates toxic gas. Avoid exposing the product to strong acids and strong oxidizing agents.

Exposure hazards to incorrect use:

- Eye contact: Causes serious eye irritation. There may be irritation and redness. The eyes may water profusely. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If irritation persists:
  Get medical attention.
- Ingestion: Harmful if swallowed. There may be soreness and redness of the mouth and throat.
- Inhalation: May cause respiratory irritation. There may be irritation of the throat with a feeling of tightness in the chest. Exposure may cause coughing or wheezing.

SMARTTRACK™ ALIGNER MATERIAL (CURRENT STANDARD INVISALIGN MATERIAL)

Q. What is the use for this product/material?

A. SmartTrack is a highly elastic, proprietary aligner material that delivers gentle, constant force to control tooth movements with Invisalign clear aligner treatment.

Q. What are the components/ingredients in the SmartTrack Material?

A. SmartTrack aligners are made of Thermoplastic Polyurethane/Co-polyester

Q. What is the material used to make SmartTrack aligner material?

A. SmartTrack material is a medical grade, high molecular weight, thermoplastic polymer. Invisalign aligners are made from SmartTrack material and are not made with latex, parabens, phthalates, glutaraldehyde, per- and polyfluorinated substances (PFAS), epoxy or Bisphenol A ("BPA"). Of course, as with any medical device, you should consult with your health professional about your aligner or retainer treatment and any applicable risks of use.

Q. Does Align's SmartTrack aligner material contain any latex, parabens, phthalate, glutaraldehyde, per- and polyfluorinated substances (PFAS), epoxy, or Bisphenol A ("BPA")?

A. SmartTrack aligner material is not made with latex, parabens, phthalates, glutaraldehyde, PFAS, epoxy or Bisphenol A ("BPA"). Of course, as with any medical device, you should consult with your health professional about your aligner treatment and any applicable risks of use.

Q. Does SmartTrack material contain any heavy metals?

A. All Invisalign aligner materials are made of medical grade, high molecular weight, thermoplastic polymers. They are not made with the heavy metals listed below. Trace elements may not be detectable in industry standard material and product tests, so our guidance is limited to the elements which are intentionally included or not included in our products.

Levels of these metals are **NOT** expected to exceed 100 ppm:

- Antimony / Antimony Compounds
- Arsenic / Arsenic Compounds
- Barium / Barium Compounds
- Beryllium / Beryllium Compounds
- Cadmium / Cadmium Compounds
- Chromium / Chromium Compounds
- Cobalt / Cobalt Compounds
- Copper / Copper Compounds
- Lead / Lead Compounds
- Manganese / Manganese Compounds
- Mercury / Mercury Compounds
- Molybdenum / Molybdenum Compounds
- Nickel / Nickel Compounds

- Selenium / Selenium Compounds
- Silver / Silver Compounds
- Tellurium / Tellurium Compounds
- Thallium / Thallium Compounds
- Tin / Tin Compounds
- Zinc / Zinc Compounds

Q. Does SmartTrack material contain any known food allergens?

A. Invisalign clear aligners are not made with a major food allergen as defined by the U.S. Food Allergen Labeling and Consumer Protection Act, or a food allergen as defined by Canadian Food Inspection Agency. These allergens include the substances listed in the table below.

Allergenic Materials	
Milk and milk products, such as:	Cow's milk, lactose with protein, lactose, cheese, yogurt, curds, butter solid, butter fat, sour cream, whey casein, caseinates, lactalbumin, hydrolysates.
Eggs and egg products, such as:	Eggs, egg whites, egg yolks, ovomucoid, ovoalbumin, mayonnaise, egg nog, albumin, globulin, lecithin, meringue, powder eggs, lysozyme,
Fish and fish products, such as:	Fish and Fish protein: Surimi, cod, Pollock, whitefish, herring, sardines, trout
Crustacean shellfish, such as:	Lobster, crayfish, shrimp, crab, prawn
Nuts and nut products, such as:	Walnuts, almonds, pecans, pistachios, hazelnut, brazil nut, cashews, hickory nuts, chest nuts, macadamia nuts, and (first) pressed nut oils, pine, filbert.
Wheat and grain products, such as:	Wheat flour, wheat germ, wheat bran gluten, spelt, high protein flour, malt, cracker meal, wheat durum flour, semolina, farina, bread crumbs, cereal extracts, buckwheat, oats, barley, triticale, rye.
Peanuts and peanut products, such as:	Peanuts, peanut butter, peanut protein, flour, cold pressed peanut oil.
Soy and soy product, such as:	Soy, miso, tofu, soy flours, texturized vegetable protein, hydrolyzed vegetable protein.
Seeds and seed products, such as:	Whole seeds, sesame, sesame seed meal, sesame seed oil, poppy, cotton, sunflower, mustard, celery
Lupine and lupine products	

Q. Are the any hazardous ingredients in the SmartTrack Material?

A. According to US regulations:

The manufacturer of the raw material for Invisalign aligners lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200. This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins listed in the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65).

B. According to the European Union regulations:

The Invisalign aligners comply to the Directive (EU) 2015/863 amendment of the RoHS 3 DIRECTIVE 2011/65/EU, RoHS-Recast, Article 4(1): Restriction of use of certain Hazardous Substances ("RoHS") and certifies that the materials used for the manufacturing of aligners do not contain more than the allowed limits of hazardous substances listed below currently set by the RoHS directive.

- Cadmium (Cd): 0.01%
- Mercury: 0.1%
- Lead (Pb): 0.1%
- Hexavalent chromium (Cr6+): 0.1%
- Polybrominated biphenyls (PBB): 0.1%
- Polybrominated diphenyl ethers (PBDE): 0.1%
- Bis (2-Ethylhexyl) phthalate (DEHP): 0.1%
- Benzyl butyl phthalate (BBP): 0.1%
- Dibutyl phthalate (DBP): 0.1%
- Diisobutyl phthalate (DIBP): 0.1%

Based on our current knowledge, testing of the raw materials and processes used in the manufacture of aligners, the Invisalign aligners meet the REACH Regulation ("EC") No 1907/2006 of the European Parliament and the Council of December 18th, 2006. To the best of our knowledge, latex, parabens, phthalates, glutaraldehyde, per- and polyfluorinated substances (PFAS), epoxy or Bisphenol A ("BPA") are not added to Invisalign aligners, Invisalign retainers and Vivera retainers, or any other of the restricted substances, published on Candidate List of Substances of Very High Concern for authorization by European Chemicals Agency ("ECHA") on January 16th, 2020. Of course, as with any medical device, you should consult with your health professional about your aligner or retainer treatment and any applicable risks of use.

Q. Are there any precautions to take during storage and manipulation or incorrect use/handling?

A. The product is stable and non-reactive under normal conditions of use, storage, and transport. Store away from incompatible materials (Strong oxidizing agents). Store away from heat sources and sunlight to avoid degradation.

VIVERA™ AND INVISALIGN RETAINER APPLIANCE MATERIALS AND INVISALIGN TEMPLATES MATERIALS - EX15, EX40

(EX40 – Vivera™ and Invisalign® Retainers, EX15 – Invisalign Templates)

Q. What is the use for these products/materials?

A. These are, EX40 – Used for Vivera and Invisalign Retainers, and EX15 – Used for Invisalign Templates

Q. What are the components/ingredients in these materials?

A. These materials are medical grade, high molecular weight, thermoplastic polymers.

Q. Does EX ("Exceed") material contain any latex, parabens, phthalate, glutaraldehyde, per- and polyfluorinated substances (PFAS), epoxy, or Bisphenol A ("BPA")?

EX material is a medical grade, high molecular weight, thermoplastic polymer. Invisalign retainers and Vivera™ retainers are not made with latex, parabens, phthalates, glutaraldehyde, PFAS, epoxy or Bisphenol A ("BPA"). Of course, as with any medical device, you should consult with your health professional about your aligner or retainer treatment and any applicable risks of use.

Q. Does EX material contain any heavy metals?

A. All aligner, retainer and template materials are made of medical grade, high molecular weight, thermoplastic polymers. They are not made with the heavy metals listed below. Trace elements may not be detectable in industry standard material and product tests, so our guidance is limited to the elements which are intentionally included or not included in our products.

Levels of these metals are NOT expected to exceed 100 ppm:

- Antimony / Antimony Compounds
- Arsenic / Arsenic Compounds

- Barium / Barium Compounds
- Beryllium / Beryllium Compounds
- Cadmium / Cadmium Compounds
- Chromium / Chromium Compounds
- Cobalt / Cobalt Compounds
- Copper / Copper Compounds
- Lead / Lead Compounds
- Manganese / Manganese Compounds
- Mercury / Mercury Compounds
- Molybdenum / Molybdenum Compounds
- Nickel / Nickel Compounds
- Selenium / Selenium Compounds
- Silver / Silver Compounds
- Tellurium / Tellurium Compounds
- Thallium / Thallium Compounds
- Tin / Tin Compounds
- Zinc / Zinc Compounds

Q. Does EX material contain any known food allergens?

A. EX aligners, retainers and templates are not made with a major food allergen as defined by the U.S. Food Allergen Labeling and Consumer Protection Act, or a food allergen as defined by Canadian Food Inspection Agency. These allergens include the substances listed in the table below.

Q. Are there any hazardous ingredients in the EX Material?

A. According to US regulations:

The manufacturer of the raw material for this material lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200. This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins listed in the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65).

B. According to the European Union regulations:

The aligners, retainers and templates made of EX material comply to the Directive ("EU") 2015/863 amendment of the RoHS 3 DIRECTIVE 2011/65/EU, RoHS-Recast, Article 4(1): Restriction of use of certain Hazardous Substances ("RoHS") and certifies that the materials used for the manufacturing of these devices do not contain more than the allowed limits of hazardous substances listed below currently set by the RoHS directive.

- Cadmium (Cd): 0.01%
- Mercury: 0.1%
- Lead (Pb): 0.1%
- Hexavalent chromium (Cr6+): 0.1%
- Polybrominated biphenyls (PBB): 0.1%
- Polybrominated diphenyl ethers (PBDE): 0.1%
- Bis (2-Ethylhexyl) phthalate (DEHP): 0.1%
- Benzyl butyl phthalate (BBP): 0.1%
- Dibutyl phthalate (DBP): 0.1%
- Diisobutyl phthalate (DIBP): 0.1%

Based on our current knowledge, testing of the raw materials and processes used in the manufacture of EX aligners, retainers and templates, these products meet the REACH Regulation ("EC") No 1907/2006 of the European Parliament and the Council of December 18th, 2006. To the best of our knowledge, latex, parabens, phthalates, glutaraldehyde, per- and polyfluorinated substances (PFAS), epoxy or Bisphenol A ("BPA") are not added to Invisalign aligners, Invisalign retainers and Vivera retainers, or any other of the restricted substances, published on Candidate List of Substances of Very High Concern for authorization by European Chemicals Agency ("ECHA") on January 16th, 2020. Of course, as with any medical device, you should consult with your health professional about your aligner or retainer treatment and any applicable risks of use.

Q. Are there any precautions to take during storage and manipulation or incorrect use/handling?

A. The product is stable and non-reactive under normal conditions of use, storage, and transport. Store away from incompatible materials (Strong oxidizing agents). Store away from heat sources and sunlight to avoid degradation.