



## Regulatory Data Sheet

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## 3M™ Clarity™ Aligners-Flex/Force

3M  
Oral Care Solutions Division  
3M Center, St. Paul, MN 55144-1000, USA  
1-888-3M HELPS (1-888-364-3577)

RDSs are available at [www.3M.com](http://www.3M.com)

### Regulations and Industry Standards

#### SDS (US OSHA)

This product is an article and therefore is not subject to the requirements of the US Occupational Safety and Health Administration's (OSHA) Hazardous Communications Standard 29 CFR 1910.1200(b)(6)(v) to provide a Safety Data Sheet (SDS).

#### EU CMRs

This product does not contain an ingredient at  $\geq 0.1\%$  that is classified as a Category 1A or 1B carcinogen, mutagen, or reproductive toxicant according to Annex VI of European Regulation 1272/2008 on Classification, Labelling, and Packaging of Dangerous Substances and Mixtures or that is classified by 3M or its vendors as a Category 1A or 1B carcinogen, mutagen, or reproductive toxicant according to the criteria laid out in European Regulation 1272/2008 on Classification, Labelling, and Packaging of Dangerous Substances and Mixtures.

#### EU Food Allergens

This product complies with Regulation (EU) 1169/2011 on the provision of food information to consumers, as there is no intentionally added component identified in Annex II of this regulation. Specifically, none of the following are intentionally added: cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame seeds, sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/L expressed as sulphur dioxide, lupin, mollusks, and/or derivatives thereof.

#### EU REACH

This product, including any article that the product is composed of, does not contain at greater than 0.1% by weight a Substance of Very High Concern (SVHC) substance identified according to Article 59 of REACH. This declaration reflects the substances on the candidate SVHC list, effective January 2024.

#### Halal

This product has not been certified Halal.

#### Kosher

This product has not been certified Kosher.

#### US FALCPA

This product complies with the United States Food Allergy Labeling and Consumer Protection Act of 2004, as there is no intentionally added milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and/or proteins thereof.

## Chemicals and/or Compounds of Interest

**Arsenic and (As) Compounds** : Not known to contain.

**Azocolorants and Azodyes** : Not known to contain.

**Beryllium and (Be) Compounds** : Not known to contain.

**Bismuth and (Bi) Compounds** : Not known to contain.

**Bisphenol A (BPA) (CAS 80-05-7)** : Not known to contain.

**Cadmium and (Cd) Compounds** : Not known to contain.

**Chromium and (Cr) Compounds** : Not known to contain.

**Cobalt and (Co) Compounds** : Not known to contain.

**Colophony (Rosin) (CAS 8050-09-7)** : Not known to contain.

**Dyes** : Not known to contain.

**Flavorings** : Not known to contain.

**Formaldehyde (CAS 50-00-0)** : Not known to contain.

**Gluten** : Not known to contain.

**Isocyanates** : Not known to contain.

**Materials of Human or Animal Origin** : Not known to contain.

**Mercury and (Hg) Compounds** : Not known to contain.

**Natural Rubber Latex** : Not known to contain.

**Nickel and (Ni) Compounds** : Not known to contain.

## Definitions

*Note: all Definitions take Disclaimers into account and apply to the “Chemicals and/or Compounds of Interest” and/or “Per and poly-fluoroalkyl Substances (PFAS)” sections only*

Terms	Definitions
Contains*	Present based on composition information disclosed by 3M suppliers, analytical testing, or both.
Not known to contain*	1. Analytical measurement for presence is not currently available; 2. If measurement is possible, a) The material has not been identified or disclosed to 3M and b) The material has not been specifically quantified or detected; OR c) Based on information from raw material suppliers, possible presence as an impurity or by-product at or below regulatory thresholds (e.g., 0.1 or 0.01 %)
Intentionally added**	Desired in the final product to provide a specific characteristic, appearance, or quality and/or to perform a specific function.
Not intentionally added**	By-product(s), impurity(ies) and/or unintended artifact(s) resulting from the formulation and/or manufacture of a material.
By-product***	A chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.
Impurity***	A chemical substance which is unintentionally present with another chemical substance (e.g., residuals, catalysts, process solvents).

\*Terms apply to the Chemicals and/or Compounds of Interest Section only (if section is present)

\*\*Terms apply to the PFAS Section only (if section is present)

\*\*\*Terms apply to both the Chemicals and/or Compounds of Interest and PFAS Sections (if section(s) are present)

Disclaimers: The information provided in this document related to material content represents 3M's knowledge and belief, which may be based in whole or in part on information provided by suppliers to 3M. This is intended to answer commonly asked questions about 3M products and is not intended to be a comprehensive listing of all substances that may be of interest or that may be regulated in this or other 3M products, nor is it intended to be a comprehensive summary of any and all regulations that may apply to this product. Where substances are listed, their listing does not infer or constitute a judgment as to their safety, environmental or health impacts. Information is supplied upon the condition that the persons receiving the same will make their own determination as

to its suitability for their purposes prior to use. Customers are encouraged to consult with legal and regulatory experts to determine applicable regulations in light of intended use of the product.

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