

Section 1. Identification

GHS product identifier : Simpli5™ Aligner; Red, White & Blue Aligner
Product code : Not available.
Other means of identification : Not available.
Product type : Solid.

Relevant identified uses of the substance or mixture and uses advised against

Product use : Dental product: Orthodontic Appliance
 This product, under the normal conditions of use, meets the definition of an "ARTICLE".
Area of application : Professional applications.

Manufacturer : **Ormco Corporation**
 1332 S. Lone Hill Avenue
 Glendora, CA 91740-5339
 Telephone no.: 1-800-854-1741

e-mail address of person responsible for this SDS : OrmcoCustCare@sybrondental.com

Emergency telephone number (with hours of operation) : CHEMTREC® (24 hours) U.S. : 1-800-424-9300 International: +1-703-527-3887

Section 2. Hazards identification

OSHA/HCS status : While this material is an article and exempted by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Classification of the substance or mixture : Not classified.
 Percentage of the mixture consisting of ingredient(s) of unknown toxicity: 15%

GHS label elements

Signal word : No signal word.
Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.
Response : Not applicable.
Storage : Not applicable.
Disposal : Not applicable.

Hazards not otherwise classified : If dust or fumes are generated during processing (e.g., brazing, cutting, grinding, sawing, and welding) hazardous chemicals could be released.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture
Other means of identification : Not available.

Ingredient name	Other names	%	CAS number
ethyl acetate	-	≥75 - ≤90	141-78-6
trimethoxypropylsilane	-	≤10	1067-25-0

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health and hence require reporting in this section.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact : No special measures are required. Get medical attention if symptoms occur.
Inhalation : No special measures required. Get medical attention if symptoms occur.
Skin contact : No special measures required. Get medical attention if symptoms occur.
Ingestion : If swallowed then seek immediate medical assistance.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact : No specific data.
Inhalation : No specific data.
Skin contact : No specific data.
Ingestion : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Specific treatments : No specific treatment.
Protection of first-aiders : In case of major fire and large quantities: No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : Do not use water jet.

Specific hazards arising from the chemical : No specific fire or explosion hazard.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
metal oxide/oxides
methanol

Special protective actions for fire-fighters : In case of major fire and large quantities: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : Low release. For professional use only. Handling of product in very small amounts or in situations where release is highly unlikely
- For emergency responders** : Low release. See also the information in "For non-emergency personnel".

Environmental precautions : No special measures are required.

Methods and materials for containment and cleaning up

- Small spill** : No special measures required.
- Large spill** : No special measures required.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : No special measures are required.
- Advice on general occupational hygiene** : No special measures are required.

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
ethyl acetate	ACGIH TLV (United States, 3/2016). TWA: 400 ppm 8 hours. TWA: 1440 mg/m ³ 8 hours. NIOSH REL (United States, 10/2013). TWA: 400 ppm 10 hours. TWA: 1400 mg/m ³ 10 hours. OSHA PEL (United States, 6/2016). TWA: 400 ppm 8 hours. TWA: 1400 mg/m ³ 8 hours.
trimethoxypropylsilane	None.

Appropriate engineering controls : No special measures are required for small quantities under normal and intended conditions of product use.

Environmental exposure controls : No special measures are required for small quantities under normal and intended conditions of product use.

Individual protection measures

Hygiene measures : No special measures are required for small quantities under normal and intended conditions of product use.

Eye/face protection : No special measures are required for small quantities under normal and intended conditions of product use.

Skin protection

Hand protection : No special protection is required.

Body protection : No special measures are required for small quantities under normal and intended conditions of product use.

Other skin protection : No special measures are required for small quantities under normal and intended conditions of product use.

Respiratory protection : No special measures are required for small quantities under normal and intended conditions of product use.

Section 9. Physical and chemical properties

Appearance

Physical state : Solid. [Round disk]

Color : Colorless./Blue.

Odor : Odorless.

Odor threshold : Not applicable.

pH : Not applicable.

Melting point : 218.33°C (425°F)

Boiling point : Not applicable.

Flash point : Not applicable.

Evaporation rate : Not applicable.

Flammability (solid, gas) : Not available.

Section 9. Physical and chemical properties

Lower and upper explosive (flammable) limits	: Not applicable.
Vapor pressure	: Not applicable.
Vapor density	: Not applicable.
Relative density	: Not applicable.
Density	: Not available.
Solubility	: Insoluble in the following materials: cold water and hot water.
Solubility in water	: Not available.
Partition coefficient: n-octanol/water	: Not available.
Auto-ignition temperature	: Not applicable.
Decomposition temperature	: Not applicable.
SADT	: Not available.
Viscosity	: Not applicable.
Flow time (ISO 2431)	: Not applicable.

Section 10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur. Under normal conditions of storage and use, hazardous polymerization will not occur.
Conditions to avoid	: No specific data.
Incompatible materials	: No specific data.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
ethyl acetate	LC50 Inhalation Vapor	Rat	4000 ppm	4 hours
	LD50 Oral	Rat	5620 mg/kg	-
trimethoxypropylsilane	LC50 Inhalation Vapor	Rat	>22200 mg/m ³	4 hours

Irritation/Corrosion

Not available.

Sensitization

Section 11. Toxicological information

Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
ethyl acetate	Category 3	Not applicable.	Narcotic effects
trimethoxypropylsilane	Category 3	Not applicable.	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of exposure : Routes of entry anticipated: Oral, Dermal, Inhalation.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.

Inhalation : No specific data.

Skin contact : No specific data.

Ingestion : No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Section 11. Toxicological information

Potential chronic health effects

Not available.

General	: No known significant effects or critical hazards.
Carcinogenicity	: No known significant effects or critical hazards.
Mutagenicity	: No known significant effects or critical hazards.
Teratogenicity	: No known significant effects or critical hazards.
Developmental effects	: No known significant effects or critical hazards.
Fertility effects	: No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Not available.

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
ethyl acetate	Acute EC50 2500000 µg/l Fresh water	Algae - Selenastrum sp.	96 hours
	Acute LC50 750000 µg/l Fresh water	Crustaceans - Gammarus pulex	48 hours
	Acute LC50 154000 µg/l Fresh water	Daphnia - Daphnia cucullata	48 hours
	Acute LC50 212500 µg/l Fresh water	Fish - Heteropneustes fossilis	96 hours
	Chronic NOEC 2400 µg/l Fresh water	Daphnia - Daphnia magna	21 days
	Chronic NOEC 75.6 mg/l Fresh water	Fish - Pimephales promelas - Embryo	32 days
	trimethoxypropylsilane	Acute EC50 >816 mg/l Fresh water	Daphnia
Acute LC50 >746 mg/l Fresh water		Fish	96 hours
Acute NOEC >816 mg/l Fresh water		Daphnia	48 hours
Acute NOEC >746 mg/l Fresh water		Fish	96 hours

Persistence and degradability

Product/ingredient name	Test	Result	Dose	Inoculum
ethyl acetate	301D Ready Biodegradability - Closed Bottle Test	100 % - 28 days	-	-
trimethoxypropylsilane	EU	54 % - Not readily - 28 days	-	-

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
ethyl acetate	-	-	Readily
trimethoxypropylsilane	-	-	Not readily

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
ethyl acetate	0.68	30	low

Section 12. Ecological information

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

United States - RCRA Toxic hazardous waste "U" List

Ingredient	CAS #	Status	Reference number
Ethyl acetate (I); Acetic acid ethyl ester (I)	141-78-6	Listed	U112

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class (es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information	-	-	-

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL and the IBC Code : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **United States inventory (TSCA 8b)**: Not determined.

Clean Air Act Section 112 : Not listed

(b) Hazardous Air Pollutants (HAPs)

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
ethyl acetate	≥75 - ≤90	Yes.	No.	No.	Yes.	No.
trimethoxypropylsilane	≤10	Yes.	No.	No.	Yes.	No.

SARA 313

Not applicable.

State regulations

Massachusetts : The following components are listed: ETHYL ACETATE; ACETIC ACID, ETHYL ESTER; DIATOMACEOUS EARTH; AMORPHOUS SILICA

New York : The following components are listed: Ethyl acetate

New Jersey : The following components are listed: ETHYL ACETATE; ACETIC ACID, ETHYL ESTER

Pennsylvania : The following components are listed: ACETIC ACID ETHYL ESTER; SILICA

California Prop. 65

None of the components are listed.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol (Annexes A, B, C, E)

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Section 15. Regulatory information

Not listed.

[UNECE Aarhus Protocol on POPs and Heavy Metals](#)

Not listed.

Section 16. Other information

[Hazardous Material Information System \(U.S.A.\)](#)

Health	0
Flammability	0
Physical hazards	0

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings are not required on SDSs under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered mark of the National Paint & Coatings Association (NPCA). HMIS® materials may be purchased exclusively from J. J. Keller (800) 327-6868.

The customer is responsible for determining the PPE code for this material.

[National Fire Protection Association \(U.S.A.\)](#)



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[Procedure used to derive the classification](#)

Classification	Justification
Not classified.	

[History](#)

Date of issue/Date of revision	: 01/26/2017
Date of previous issue	: No previous validation
Version	: 1
Key to abbreviations	: ATE = Acute Toxicity Estimate BCF = Bioconcentration Factor GHS = Globally Harmonized System of Classification and Labelling of Chemicals IATA = International Air Transport Association IBC = Intermediate Bulk Container IMDG = International Maritime Dangerous Goods LogPow = logarithm of the octanol/water partition coefficient

Date of issue/Date of revision	: 01/26/2017	Date of previous issue	: No previous validation	Version	: 1	10/11
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Section 16. Other information

MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
UN = United Nations

References : HCS (U.S.A.)- Hazard Communication Standard
International transport regulations

✔ Indicates information that has changed from previously issued version.

Notice to reader

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