

# SAFETY DATA SHEET

## 1. Product and Company Information

**Product Name:** Argen Clear Aligners

### Details of the Supplier of the Safety Data Sheet:

 The Argen Corporation  
5855 Oberlin Drive  
San Diego, CA 92121 U.S.A.

**Trade Name & Synonyms:** Argen Aligners

**Chemical Family:** Copolyester – Polyurethane Composite

## 2. Hazards Identification

**According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200**

### Classification of the product

No need for classification according to GHS criteria for this product.

### Label elements

The product does not require a hazard warning label in accordance with GHS criteria. **Hazards not otherwise classified**

No specific dangers known, if the regulations/notes for storage and handling are considered.

### Labeling of special preparations (GHS):

UNDER THERMOFORMING OR PROCESSING CONDITIONS, WEAR PERSONAL PROTECTIVE EQUIPMENT TO PREVENT THERMAL BURNS.

**According to Regulation 1994 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200**

### Emergency overview

CAUTION:

UNDER THERMOFORMING OR PROCESSING CONDITIONS, WEAR PERSONAL PROTECTIVE EQUIPMENT TO PREVENT THERMAL BURNS. Use with local exhaust ventilation.

## 3. Composition / Information on Ingredients

**According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200**

This product does not contain any components classified as hazardous under the referenced regulation.

**According to Regulation 1994 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200**

CAS Number	Content (W/W)	Chemical name
Proprietary	20 – 80%	THERMOPLASTIC URETHANE
Proprietary	20 – 80%	COPOLYESTER

## 4. First Aid Measures

### Description of first aid measures

#### General advice:

Remove contaminated clothing.

#### If inhaled:

Remove the affected individual into fresh air and keep the person calm. Assist in breathing if necessary. Immediate medical attention required.

#### If on skin:

Wash affected areas thoroughly with soap and water. If irritation develops, seek medical attention.

Skin contact with hot molten substance/product may cause thermal burns.

#### If in eyes:

In case of contact with the eyes, rinse immediately for at least 15 minutes with plenty of water. If irritation develops, seek medical attention.

#### If swallowed:

Rinse mouth and then drink plenty of water. Do not induce vomiting. Immediate medical attention required.

### Most important symptoms and effects, both acute and delayed

Symptoms: No significant reaction of the human body to the product known.

Hazards: No hazards anticipated.

### Indication of any immediate medical attention and special treatment needed

#### Note to physician

Treatment: Treat according to symptoms (decontamination, vital functions), no known specific antidote.

## 5. Fire and Explosion Data

### Extinguishing media

Suitable extinguishing media:

Water spray, dry powder, carbon dioxide, foam

### Special hazards arising from the substance or mixture

Hazards during fire-fighting:

No particular hazards known.

### Advice for fire-fighters

Protective equipment for fire-fighting:

Firefighters should be equipped with self-contained breathing apparatus and turn-out gear.

### Further information:

In case of fire and/or explosion do not breathe fumes.

## 6 Accidental Release Measures

### Personal precautions, protective equipment and emergency procedures

No special precautions necessary.

### Environmental precautions

No special precautions necessary.

### Methods and material for containment and cleaning up

Spills should be contained and placed in suitable containers for disposal.

## 7. Handling and Storage

### Precautions for safe handling

Provide suitable exhaust ventilation when thermoforming or trimming.

Protection against fire and explosion:

No explosion proofing necessary.

### Conditions for safe storage, including any incompatibilities

Segregate from foods and animal feeds.

Suitable materials for containers: carbon steel (iron), High density polyethylene (HDPE), Low density polyethylene (LDPE), Stainless steel 1.4301 (V2)

Further information on storage conditions: Avoid extreme heat. Avoid deposition of dust.

Storage stability:

Protect against moisture.

## 8. Exposure Control/Personal Protection

### Advice on system design:

Provide local exhaust ventilation to control dust.

### Personal protective equipment

#### Respiratory protection:

Wear a NIOSH-certified (or equivalent) organic vapor/particulate respirator as needed.

#### Hand protection:

Wear gloves to prevent contact during mechanical processing and/or hot melt conditions.

#### Eye protection:

Wear splash goggles to protect from hot molten substance/product.

#### Body protection:

Body protection not required.

### General safety and hygiene measures:

Wear protective clothing to prevent contact during mechanical processing and/or hot melt conditions. Avoid inhalation of dust.

When using, do not eat, drink or smoke. Hands and/or face should be washed before breaks and at the end of the shift. At the end of the shift the skin should be cleaned and skin-care agents applied.

## 9. Physical and Chemical Characteristics

Form:	sheet	
Odour:	mild	
Odour threshold:		not applicable
Colour:	colourless	
pH value:		not applicable
Melting point:	150-230 °C	
Boiling point:		not applicable
Sublimation point:		No applicable information available
Flash point:	>300 °C	
Flammability:	not flammable	
Lower explosion limit:		For solids not relevant for classification and labeling.
Upper explosion limit:		For solids not relevant for classification and labeling.
Autoignition:		not applicable
Vapour pressure:		not applicable

Relative density:	1.12-1.2	
Bulk density:	500-1200 kg/m <sup>3</sup>	(20 °C)

## 10. Stability and Reactivity

### Reactivity

Corrosion to metals:

No corrosive effect on metal.

Oxidizing properties:

Not an oxidizer.

### Chemical stability

The product is stable if stored and handled as prescribed/indicated.

### Possibility of hazardous reactions

The product is chemically stable.

No hazardous reactions if stored and handled as prescribed/indicated.

### Conditions to avoid

No conditions known that should be avoided.

### Incompatible materials

No substances known that should be avoided.

### Hazardous decomposition products

Decomposition products:

Carbon monoxide, carbon dioxide, hydrogen cyanide

Thermal decomposition:

No decomposition if stored and handled as prescribed/indicated.

< 230 °C

Thermal decomposition above the indicated temperature is possible.

Prolonged thermal loading can result in products of degradation being given off.

## 11. Toxicological Information

### Primary routes of exposure

Routes of entry for solids and liquids are ingestion and inhalation, but may include eye or skin contact.

Routes of entry for gases include inhalation and eye contact. Skin contact may be a route of entry for liquefied gases.

### Acute Toxicity/Effects

#### Acute toxicity

Assessment of acute toxicity: Inhalation of particulates may cause respiratory tract irritation. Ingestion may cause gastrointestinal disturbances. Contact with molten product may cause thermal burns. The resin in pelleted form poses a low hazard.

#### Oral

Type of value: LD50

Species: rat

Value: > 5,000 mg/kg

#### Assessment other acute effects

Assessment of STOT single:

Based on the available information there is no specific target organ toxicity to be expected after a single exposure.

#### Irritation / corrosion

Assessment of irritating effects: Not irritating to the eyes. Not

irritating to the skin.

#### Sensitization

Assessment of sensitization: The chemical structure does not suggest a sensitizing effect.

#### Aspiration Hazard

No aspiration hazard expected.

#### **Chronic Toxicity/Effects**

##### Repeated dose toxicity

Assessment of repeated dose toxicity: No known chronic effects. Repeated exposure to the substance by dermal administration leads to effects similar to those found after single exposure. Repeated exposure to the substance by inhalative administration leads to effects similar to those found after single exposure. Repeated exposure to the substance by oral administration leads to effects similar to those found after single exposure.

##### Genetic toxicity

Assessment of mutagenicity: The chemical structure does not suggest a specific alert for such an effect.

##### Carcinogenicity

Assessment of carcinogenicity: The chemical structure does not suggest a specific alert for such an effect.

##### Reproductive toxicity

Assessment of reproduction toxicity: The chemical structure does not suggest a specific alert for such an effect.

##### Teratogenicity

Assessment of teratogenicity: The chemical structure does not suggest a specific alert for such an effect.

#### Endocrine Disruptor Information

Bisphenol A is not used in the manufacture or formulation of this product. We do not test this product for this chemical substance.

#### Other Information

The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

#### **Symptoms of Exposure**

No significant reaction of the human body to the product known.

#### Medical conditions aggravated by overexposure

Data available do not indicate that there are medical conditions that are generally recognized as being aggravated by exposure to this substance/product.

## **12. Ecological Information**

### **Toxicity**

#### Aquatic toxicity

Assessment of aquatic toxicity:

There is a high probability that the product is not acutely harmful to aquatic organisms.

### **Persistence and degradability**

#### Assessment biodegradation and elimination (H<sub>2</sub>O)

Poorly biodegradable.

#### Elimination information

Poorly biodegradable.

### **Bioaccumulative potential**

#### Bioaccumulation potential

The product has not been tested.

### **Mobility in soil**

Assessment transport between environmental compartments Due to the product characteristics the test is impossible.

### **Additional information**

Absorbable organically-bound halogen (AOX):

This product contains no organically-bound halogen.

Other ecotoxicological advice:

The product has not been tested. The statement has been derived from substances/products of a similar structure or composition.

## **13. Disposal Considerations**

### **Waste disposal of substance:**

Incinerate in a licensed facility. Do not discharge substance/product into sewer system. Dispose of in a licensed facility.

### **Container disposal:**

Dispose of in accordance with national, state and local regulations.

## **14. Transport Information**

Land transport	
USDOT	Not classified as a dangerous good under transport regulations
Sea transport	
IMDG	Not classified as a dangerous good under transport regulations
Air transport	
IATA/ICAO	Not classified as a dangerous good under transport regulations

## **15. Regulatory Information**

Federal Regulations		
Registration Status:		
Chemical	TSCA, US	released/listed
EPCRA 311/312 (Hazard categories):		Not hazardous;
NFPA Hazard codes:		
Health: 1	Fire: 0	Reactivity: 0
HMIS III rating		
Health: 1	Flammability: 0	Physical hazard: 0

## **16. Other Information**

SDS Prepared by: Argen, Corporation, San Diego, CA