

**G&H® Wire Company**2165 Earlywood Drive  
Franklin, IN 46131

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**MATERIAL SAFETY DATA SHEET DIRECTIVE 91/155/EEC**

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**1. SUBSTANCE/PREPARATION AND COMPANY IDENTIFICATION**

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- 1.1 Chemical Nature, Sales Name, Use: PVC 40 SHA Blue Cristal Ref 7607, NEOsmile™ soft tooth positioners with lot numbers above C20575.
- 1.2 Company Identification:  
G&H Wire Company  
2165 Earlywood Drive  
Franklin, IN 46131  
Telephone: 317-346-6655  
Facsimile: 317-346-6663
- 1.3 Emergency Contact: 317-346-6655

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**2. COMPOSITION/INFORMATION ON INGREDIENTS**

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- 2.1 Ingredients:  
Polyvinyl Chloride, CAS # 9002-86-2  
Phthalate Free Plasticizer, CAS 1664-12-789-8, 1,2-Cyclohexanedicarboxylic acid, diisononyl ester. Material is free of DEHP, the plasticizer that makes PVC a hazard.

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**3. HAZARDS IDENTIFICATION**

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No adverse health effects are expected

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**4. FIRST-AID MEASURES**

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- 4.1 Inhalation:
- 4.2 Skin Contact: Burns from contact with melting material
- 4.3 Eye Contact: Irrigate with eyewash solution or clean water the same as when any foreign object is in the eye.
- 4.4 Ingestion Obtain medical attention if ill effects occur

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**5. FIRE-FIGHTING MEASURES**

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- 5.1 Suitable Extinguishing Media: Dry powder, water mist, foam, carbon dioxide
- 5.2 Unsuitable Extinguishing Media: Not known
- 5.3 Particular Hazards: Thermal decomposition in toxic and corrosives; chloric gas, carbon monoxide and micro particulates of carbon may provide pulmonary suffocation.
- 5.4 Protective Equipment for Fire-Fighters: Self contained breathing apparatus and protective clothing

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**6. ACCIDENTAL RELEASE MEASURES**

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- 6.1 Personal Precautions: Sweep or vacuum up. Store in suitable container for disposal
- 6.2 Environmental Precautions: NA
- 6.3 Cleaning Methods: NA

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## 7. HANDLING AND STORAGE

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- 7.1 Handling: Solid granules can present a slipping hazard if spilled
- 7.2 Storage: Provide adequate ventilation and avoid inhalation of vapors from hot molten material. Keep packaging closed.
- 7.3 Storage Conditions: Store at room temperature in a dry, adequately ventilated area. Keep away from heat and sources of ignition

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## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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Personal Protection- Observe good industrial hygiene. Wear suitable industrial clothing along with appropriate eye protection and gloves.

Exposure Control- When processing the material provide general ventilation and preferable local extraction near large area of exposed molten material.

OES = Occupational Exposure Standard

STEL = Short Term Exposure Limit

TWA = Time Weighted Average

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

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- 9.1 Form: Granular solid
  - Color: Varies with density
  - Odor: Slight Mint Scent included in finished tooth positioners
- 9.2 Change of State: Decomposition is dependent on both time and temperature but will occur increasingly rapid if left standing above 150°
  - Melting Point/Range:
  - Boiling Point:
- 9.3 Flash Point
- 9.4 Ignition Point:
- 9.5 Vapor Pressure (20°C):
- 9.6 Density (20°C):
- 9.7 Solubility in: Water (20°C): Insoluble
  - Organic Solvent (20°C):
- 9.8 PH-Value (at 10g/1H<sub>2</sub>O):
- 9.10 Viscosity (20°C):

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## 10. STABILITY AND REACTIVITY

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- 10.1 Do not heat the tooth positioner to the decomposition temperature limit.
- 10.2 Conditions to Avoid: None under range of normal use.
- 10.3 Materials to Avoid: Separate from oxidizing or acid agents up to 60° C
- 10.4 Hazardous Decomposition Products: At high temperature, release of the corrosive vapors of hydrogen chloride, toxic vapors of carbon monoxide and particulates.

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## 11. TOXICOLOGICAL INFORMATION

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- 11.1 Oral Toxicity: No risk under normal conditions
- 11.2 Inhalation: At high temperatures decomposition products are irritants even corrosive for skin, eyes and respiratory.
- 11.3 Skin Irritation: no risk under normal conditions
- 11.4 Sensitization: NA
- 11.5 Eye Irritation: No risk under normal conditions

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## 12. ECOLOGICAL INFORMATION

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- 12.1 Acute Toxicity in Fish (LC-50/48h) No special precautions to take.
- 12.2 Bacteria Toxicity (EC-0): NA
- 12.3 Biodegradability: Material is not biodegradable, recycle per local regulations.
- 12.4 Further Details: All official scientific studies do not reveal the PVC induces risk in humans during the normal use of the finished product.

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### 13. DISPOSAL CONSIDERATIONS

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- 13.1 Product: If possible recycle otherwise disposal should be in accordance with local, state, or national legislation. Bury in an authorized landfill or incinerate under approved controlled conditions.
- 13.2 Packaging: NA
- 13.3 Waste Disposal Code: NA

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### 14. TRANSPORT INFORMATION

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- 14.1 Overland Transport ADR/RID/GGVS/GGVE: Not classified as hazardous for transport.
- 14.2 Sea Transport GGVSEA/IMDG-Code:
- 14.3 Air Transport ICAO/IATA-DGR:
- 14.4 Inland Waterway Transport ADNR:
- 14.5 Further Details:

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### 15. REGULATORY INFORMATION

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- 15.1 Directives:
  - Directive 2002/72/CE, on plastic materials in contact with food
  - Directive 2005/84/CE on limitation of hazard matter
  - Standard NF EN 71-3 (Sept 2003) on toys security-part III-release of elements
  - European Resolution AP9\*() 1: On colorings in plastic materials intended to be in contact with food.
  - Regulatory CE 2004/1935, on materials and objects intended to be in contact with food.
  - Medical Device Directive 93/42 CEE: This product is Class I

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### 16. OTHER INFORMATION

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- 16.1 The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. Therefore, it should not be construed as guaranteeing specific properties.
- 16.2 Revision Date: February 9, 2009