Safety Data Sheet

Bioclear Plastic Instruments

1. Identification

Product identifier used on the label

BT Gauge
Go/No-Go Probe

Recommended use: See IFU provided by Bioclear

* The “Recommended use” identified for this product is provided solely to comply with a Federal requirement and is not part of the seller's published specification. The terms of this Safety Data Sheet (SDS) do not create or infer any warranty, express or implied, including by incorporation into or reference in the seller's sales agreement.

Details of the supplier of the safety data sheet

Company Information:

MANUFACTURER/DISTRIBUTOR
Bioclear Matrix Systems
By Dr David Clark
3802 South Warner Street, Suite A
Tacoma, WA 98409
USA

PHONE NUMBERS
Product Information 1-855-712-5327

Other means of identification

Synonyms: POLYSULFONE

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.

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

3. Composition / Information on Ingredients

Body Ingredients

Ingredient Name	Content (Range by Percentage)	CAS Number
Polysulfone (PSU)	>= 80.0 - <= 100 %	25154-01-2

Colored-tip Ingredients

Ingredient Name	Content (Range by Percentage)	CAS Number
2-butoxyethyl acetate	20 - 25%	112-07-2
Bisphenol A/Epichlorhydrin Based Epoxy Resin	10 – 20%	25068-38-6
Cyclohexanone	5 – 10%	108-94-1
Hydrocarbons, C10, aromatics, <1% naphthalene	2.5 – 5%	
xylene	2.5 – 5%	1330-20-7

Toluene diisocyanate, oligomeric reaction products with 2,2'-oxydiethanol and propylidenetrimethanol	8 - 12 %	53317-61-6
n-butyl acetate	3 - 8 %	123-86-4

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 or the environment and hence require reporting in this section.

4. First-Aid Measures

Description of first aid measures

General advice:

Avoid contact with the skin, eyes and clothing. Remove contaminated clothing.

If inhaled: N/A

If on skin: Instrument should not react to skin, however, if an allergic reaction occurs, remove from patient and then follow allergy procedures.

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: Ingestion is not likely in the available physical form. If ingested, seek medical attention.

Most important symptoms and effects, both acute and delayed

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

Hazards: No hazard is expected under intended use and appropriate handling.

Indication of any immediate medical attention and special treatment needed

Note to physician:

Treatment: Treat symptomatically.

5. Fire-Fighting Measures

Extinguishing media

Suitable extinguishing media: water spray, foam, dry powder

Special hazards arising from the substance or mixture

Hazards during fire-fighting:

carbon monoxide, Sulphur dioxide, sulphur trioxide, can be emitted at > 400 °C

Under special fire conditions traces of other toxic substances are possible. Formation of further decomposition and oxidation products depends upon the fire conditions.

Advice for fire-fighters

Protective equipment for fire-fighting:

Wear a self-contained breathing apparatus.

Further information:

Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

6. Accidental release measures

Further accidental release measures:

Personal precautions, protective equipment and emergency procedures : N/A

Environmental precautions

This product is not regulated by RCRA. This product is not regulated by CERCLA ('Superfund').

No special precautions necessary.

Methods and material for containment and cleaning up

For small amounts: Pick up with suitable appliance and dispose of.

For large amounts: Pick up with suitable appliance and dispose of.

Reclaim for processing if possible.

7. Handling and Storage

Precautions for safe handling

Protection against fire and explosion:

Take precautionary measures against static discharges.

Conditions for safe storage, including any incompatibilities

The product in undamaged packing need not be stored separately.

Further information on storage conditions: Keep container tightly closed. Avoid deposition of dust.

8. Exposure Controls/Personal Protection

Advice on system design: N/A

Personal protective equipment: N/A

Respiratory protection: N/A

Hand protection: N/A

Eye protection: N/A

Body protection: N/A

General safety and hygiene measures: No special precautions necessary. After use of gloves apply skin-cleaning agents and skin cosmetics.

9. Physical and Chemical Properties

Appearance (physical state, color, etc.):	Body primarily of solid white material with a colored tip
Odor:	Odorless
Odor Threshold:	N/A
pH value:	N/A
Initial boiling point and boiling range:	The product decomposes therefore not determined
Flash point:	Not self-igniting
Evaporation rate:	N/A
Flammability (solid, gas):	Not self-igniting
Upper/lower flammability or explosive limits:	For solids not relevant for classification and labelling.
Vapor pressure:	N/A
Relative density:	No data available
Solubility(ies):	Insoluble
Partition coefficient: n-octanol/water:	N/A
Auto-ignition temperature:	570˚ C (DIN 54836)
Decomposition temperature:	> 400 °C Thermal decomposition above the indicated temperature is possible.
Viscosity:	Not applicable, the product is a solid insoluble

10. Stability and Reactivity

Reactivity

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

Oxidizing properties:

not fire-propagating

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 known.

Conditions to avoid

Temperature: > 400 degrees Celsius

Incompatible materials

No substances known that should be avoided.

Hazardous decomposition products

Decomposition products:

Hazardous decomposition products: carbon monoxide, carbon dioxide, phenol, Water, Benzenesulfonic acid, 2(or 4)-methyl-, sulphur trioxide, Sulphur dioxide

Thermal decomposition: > 400 °C

Thermal decomposition above the indicated temperature is possible.

11. Toxicological information

Acute Toxicity/Effects

Acute toxicity

Assessment of acute toxicity: Contact with molten product may cause thermal burns. The resin in pelleted form poses a low hazard.

Assessment other acute effects

No applicable information available.

Irritation / corrosion

Assessment of irritating effects: Thermal decomposition products of the substance can irritate the eyes, skin, and respiratory tract.

Sensitization

Assessment of sensitization: Based on our experience and the information available, no adverse health effects are expected if handled as recommended with suitable precautions for designated uses.

Aspiration Hazard

No aspiration hazard expected.

Chronic Toxicity/Effects

Repeated dose toxicity

Assessment of repeated dose toxicity: Based on our experience and the information available, no adverse health effects are expected if handled as recommended with suitable precautions for designated uses.

Genetic toxicity

Assessment of mutagenicity: Based on our experience and the information available, no adverse health effects are expected if handled as recommended with suitable precautions for designated uses.

Carcinogenicity

Assessment of carcinogenicity: Based on our experience and the information available, no adverse health effects are expected if handled as recommended with suitable precautions for designated uses.

Reproductive toxicity

Assessment of reproduction toxicity: Based on our experience and the information available, no adverse health effects are expected if handled as recommended with suitable precautions for designated uses.

Other Information

Based on our experience and the information available, no adverse health effects are expected if handled as recommended with suitable precautions for designated uses.

Symptoms of Exposure

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

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. The product has not been tested. The statement has been derived from the structure of the product.

Persistence and degradability

Assessment biodegradation and elimination (H2O)

Experience shows this product to be inert and non-degradable.

The product is virtually insoluble in water and can thus be separated from water mechanically in suitable effluent treatment plants.

Bioaccumulative potential

Bioaccumulation potential

The product will not be readily bioavailable due to its consistency and insolubility in water.

13. Disposal considerations

Waste disposal of substance:

Check for possible recycling. Incinerate in suitable incineration plant, observing local authority regulations.

Container disposal:

Packs must be completely emptied.

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: Medical Device FDA, US released / listed

EPCRA 311/312 (Hazard categories): Not hazardous;

Not hazardous;

CA Prop. 65:

WARNING: THIS PRODUCT CONTAINS A CHEMICAL(S) KNOWN TO THE STATE OF CALIFORNIA TO CAUSE BIRTH DEFECTS OR OTHER REPRODUCTIVE HARM.

NFPA Hazard codes:
Health : 1 Fire: 1 Reactivity: 0 Special:

HMIS III rating
Health: 1 Flammability: 1 Physical hazard:0

16. Other Information

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This information is based upon technical information believed to be reliable. It is subject to revision as additional knowledge and experience is gained.

END OF DATA SHEET