

MATERIAL SAFETY DATA SHEET

according to Regulation (EC) No 1907/2006 of the European Parliament and of the Council

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1 Identification of the substance or preparation	<u>Ena Soft</u> (product code: EH2TS2_EHTS2) <u>Ena Soft Flow</u> (product code: EHTSF_EHTSF1)
1.2 Use of the substance/preparation:	Light curing elastic material for temporary restorations.
1.3 Company/undertaking identification:	Manufacturer Micerium S.p.A Via G. Marconi 83 16036 Avegno (GE) -Italy Phone: +39. 0185. 7887870 fax +39. 0185. 7887970
1.4 Emergency telephone:	Poison Control Center San Martino Hospital (Genova, Italy) Phone: +39 010 352808 (available 24 hours/ 24)

2. HAZARDS IDENTIFICATION

2.1 Substance or mixture classification	Skin sens. 1 – H317 Skin Irrit. 2; Eye irrit. 2; Skin sens.1; H315, H319, H317
2.2 Label elements	Labelling according to Regulation (EC) No 1272/2008: The product is classified and labelled according to the CLP regulation.
2.3 Other hazards	This product does not contain any PBT or vPvB

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Main ingredients: Diurethane dimethacrylate, mixture of isomers

3.2 Mixtures:

Common name for the compound	CAS-number	Content	Hazard and precautionary statement
Diurethane dimethacrylate, mixture of isomers	72869-86-4	50~70 5~10 (Ena Soft)	Skin Sens. 1; H317
2-Hydroxyethyl methacrylate	868-77-9	15~25 (Ena Soft Flow)	Skin Irrit. 2; Eye Irrit. 2; Skin sens. 1: H315, H319; H317
Camphorquinone	10373-78-1	<0.1 (Ena Soft) <0.3 (Ena Soft Flow)	Not classified

4. FIRST AID MEASURES

4.1 First aid measures' description: May be irritating to eyes, respiratory system, skin. Prolonged or repeated contact with methacrylate may cause sensitization. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.

Measure to be adopted when:

- **It contacts eyes:** Flush eyes with water. Get medical attention if irritation develops or persist.
- **It contacts skin:** Wash with soap and water. Get medical attention if irritation develops or persist.
- **Inhaled:** Rest in the fresh air and seek medical advice if necessary.
- **Ingested:** Try to induce vomiting. Get medical attention if any discomfort continues.

4.2 Most important symptoms and effects, both acute and delayed:
Ingestion – Slightly irritating (Digestive system).
Skin contact - Slightly irritating. May cause sensitization by skin contact.
Eye contact - Slightly irritating.

4.3 Indication of any immediate medical attention and special treatment needed: CAUTION! First aid personnel must be aware of own risk during rescue! Wear suitable protective clothing.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media: Water spray, fog, or mist, foam, dry chemical, carbon dioxide (CO₂)

Extinguishing media which shall not be used for safety reasons: NA

5.2 Special exposure hazards arising from the substance or from the mixture: NA

5.3 Recommendation for firefighters: Evacuate all personnel, use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.

Special protective equipment for firefighters: No special protective actions for fire-fighters are anticipated.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective devices and procedures in case of emergency: Ventilate area. Wear safety glasses, gloves and lab coat.

6.2 Environmental precautions: Avoid release to the environment.

6.3 Measures for cleaning/collecting: Collect as much of the spilled material as possible. Place in a closed container approved for transportation by appropriate authorities. Seal the container. Dispose of collected material as soon as possible.

6.4 Reference to other sections NA

(If appropriate refer to headings 8 and 13)

7. HANDLING AND STORAGE

7.1 Precautions for safe Handling: All handling must take place in well-ventilated area.

Indications in case of fire and explosion

7.2 Conditions for safe Storage including any incompatibilities: Store in a cool, dark place (0-25°C, 32-77°F). Keep away from heat, direct sunlight, sparks and open flames.

7.3 Specific use(s): Dental material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Further information on the structure of technical systems:

8.1 Exposure limit values: NA

Further information Do not smoke in work area! Wash hands at the end of each work shift and before eating, smoking and using the toilet. Wash promptly with soap & water if skin becomes contaminated. Promptly remove any clothing that becomes contaminated. Use appropriate skin cream to prevent drying of skin. When using do not eat, drink or smoke.

8.2 Exposure controls:

8.2.1 Suitable technical checks: Wear appropriate clothing to prevent any possibility of skin contact.

8.2.2 Individual protection measures, such as personal protective equipment:

8.2.2.a Eye/face protection: Wear approved safety goggles.

8.2.2.b Hand/skin protection: Wear protective gloves.

8.2.2.c Respiratory protection: In case of inadequate ventilation use suitable respirator.

8.2.2.d Thermal hazard: NA

8.2.3 Environmental exposure controls: Provide adequate general and local exhaust ventilation

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

Aspect:	Paste	
Physical state:	Paste	
Colour:	Yellow, blue	
Odor (odor threshold/pH):	Odor free	
Fusion point/freezing point:	ND	Relative density: <1
Boiling point/boiling range:	NA	Solubility: ND
Flash point:	ND	
Flammability (solid, gas):	ND	Partition coefficient: n-octanol/water: ND
Upper / lower flammability or explosive limits		Viscosity: ND
Explosive properties:	ND	Vapor pressure: < 1 mm Hg / 133 Pa / Id: B
Oxidizing properties:	ND	Vapor density: ND
Decomposition temperature:	ND	
Auto-ignition temperature:	ND	Evaporation rate: ND

9.2 Other information:

Miscibility:	ND	Gas group: ND
Fat solubility (solvent — oil to be specified):	ND	
Conductivity:	ND	

10. STABILITY AND REACTIVITY

10.1 Reactivity	This material is considered to be non-reactive under normal use conditions.
10.2 Chemical stability	Stable under normal temperature conditions and recommended use.
10.3 Possibility of dangerous reactions	ND
10.4 Conditions to avoid:	Keep away from heat, sparks and open flame. Protect against direct sunlight.
10.5 Incompatible materials	Strong oxidizing agents.
10.6 Hazardous decomposition products:	Toxic gases are generated when heated.

11. TOXICOLOGICAL INFORMATION

LD/LC50 values relevant for classification: ND

11.1 Information on toxicological effects

11.1.1 Acute toxicity:	ND
11.1.2 Skin contact:	Slightly irritating
11.1.3 Eye contact:	Slightly irritating
11.1.4 Respiratory/skin sensitisation:	May cause sensitization by skin contact
11.1.5 Germ cell mutagenicity:	ND
11.1.6 Carcinogenicity:	Not listed
11.1.7 Reproductive toxicity	ND

11.1.8 Specific target organ toxicity (STOT) single exposure:	ND
11.1.9 Specific target organ toxicity (STOT) repeated exposure:	ND
11.1.10 Danger in case of aspiration	ND

12. ECOLOGICAL INFORMATION

12.1 Toxicity:	ND
Aquatic toxicity	ND
12.2 Persistence and degradability	ND
12.3 Bioaccumulative potential:	ND
12.4 Mobility:	ND
12.5 Results of PBT and vPvB assessment	This product does not contain PBT or vPvB substances.
PBT:	
vPvB:	
12.6 Other adverse effects:	Not known

13. DISPOSAL CONSIDERATIONS

13.1 Disposal methods:	
Advice	Dispose in accordance with local authority requirements.
Uncleaned packaging	Dispose in accordance with local authority requirements.
Advice / Recommended detergent	NA

14. INFORMATION ON TRANSPORT

Indicate for each, where appropriate:

UN number	NA
class	ND
proper shipping name	NA
Packing group	NA
Marine pollutant	No
Other applicable information	ND
14.1 UN number:	NA
14.2 UN shipping name:	ND
By sea (IMDB):	NA
By road (ADR):	NA
By air (ICAO / IATA):	NA
14.3 Transport hazard class:	
Class:	ND
Label:	No transport warning sign required.
14.4 Packing group:	ND
14.5 Environmental hazard:	NA
14.6 Special precautions for users:	NA
Kemler number:	ND
EMS number:	ND

Legend: NA = not applicable; ND = not available data

Storage category:	ND
14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code	NA

* 15. REGULATORY INFORMATION

15.1 Legislative and regulatory provisions on health, safety and environment specific to the substance or mixture It complies with the requirements of CE, FDA, HEALT CANADA, JPAL regulations, and other countries whose laws are harmonized by ISO 13485.

15.2 Evaluation of chemical safety: ND

16. OTHER INFORMATION

16.1 List of relevant phrases: Skin sens. 1 – H317
Skin Irrit. 2; Eye irrit. 2; Skin sens.1; H315, H319, H317

16.2 Training advice: NA

16.3 Recommended restrictions on use: Only for professional use

16.4 Further information: ND

16.5 Sources of key data used to compile the Safety Data Sheet: The information in this Safety Data Sheet is believed as to be correct as of the date issued. It is stated only as guidance for safe handling, use, processing, storage, transport, and disposal. Thus, it is not to be considered a warranty or representation for which Micerium S.p.A. takes any kind of legal responsibilities takes Micerium S.p.A. no regal responsibility for any damages stemming from the misuse of mishandling of this product.

* **16.6 Changes from the previous version (if available):** Introduction of data about new Ena Soft Flow, adjustment to the new form and amendments of CE 1907/2006. Reference regulatory update.

16.7 Released by: Micerium S.p.A.