iccoraing to 1907/2000/EC, Artic

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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name: <u>ENA Bond</u>
Article number: COSM300A/A2

• 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.

· Application of the substance / the mixture Dental bonding material

· 1.3 Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Micerium spa., Via G. Marconi, 83 - 16036 Avegno (GE), Italy, Tel.: +39-0185-7887870, Fax: +39-0185-7887970

• Further information obtainable from: Dr. Eugenio Miceli

· 1.4 Emergency telephone number:

Poison Control Center San Martino Hospital (Genoa, Italy) Tel.: +39-010-352808 (available 24 h)

SECTION 2: Hazards identification

· 2.1 Classification of the substance or mixture

· Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

STOT SE 3 H335 May cause respiratory irritation.

· 2.2 Label elements

· Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

• Hazard pictograms



· Signal word Warning

	nining components of labelling: vith the exception of thosespecified elsewhere in this Annex
· Hazard statem	
H315 Causes s	kin irritation.
H319 Causes s	verious eye irritation.
H335 May cau	se respiratory irritation.
· Precautionary	statements
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves / eye protection / face protection.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+1	P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
· 2.3 Other haze	urds
· Results of PB2	T and vPvB assessment
· PBT: Not appl	

• **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

- · 3.2 Mixtures · Description:
- Solution of modified acrylic acid, polyacrylic acid, methacrylate, catalysts and stabilisators in ethanol

· Dangerous components:				
	methacrylate with the exception of thosespecified elsewhere in this Annex	10-25%		
	♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 Specific concentration limit: STOT SE 3; H335: $C \ge 10 \%$			
CAS: 64-17-5	ethanol	2.5-10%		
EINECS: 200-578-6	🚸 Flam. Liq. 2, H225			
. Additional informat	ion For the wording of the listed hazard phrases refer to section 16			

Additional information For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- 4.1 Description of first aid measures
- After inhalation Supply fresh air; consult doctor in case of complaints.
- · After skin contact Immediately wash with water and soap and rinse thoroughly.
- · After eye contact Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing If symptoms persist consult doctor.
- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

• 5.1 Extinguishing media

- · Suitable extinguishing agents
- Water spray

Carbon dioxide

Fire-extinguishing powder

Foam

• For safety reasons unsuitable extinguishing agents Water with full jet.

- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- Protective equipment: Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Do not inhale vapours.
 Wear protective equipment. Keep unprotected persons away. Keep away from ignition sources
 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
 6.3 Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose contaminated material as waste according to item 13. Ensure adequate ventilation.
 6.4 Reference to other sections See Section 7 for information on safe handling
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

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SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling No special measures required.
- · Information about fire and explosion protection:
- Keep ignition sources away Do not smoke.
- Protect against electrostatic charges.
- 7.2 Conditions for safe storage, including any incompatibilities
- · Storage
- Requirements to be met by storerooms and receptacles: Storage between 3°C and 25 °C.
- · Information about storage in one common storage facility: Store away from foodstuffs.
- Further information about storage conditions: Store in cool, dry conditions in well sealed receptacles.
- · Storage class 3A
- 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace:

64-17-5 ethanol

WEL Long-term value: 1920 mg/m³, 1000 ppm

- Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see item 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures Wash hands before breaks and at the end of work.
- · Respiratory protection: Not necessary if room is well-ventilated.
- · Hand protection Solvent resistant gloves
- *Material of gloves* Butyl rubber, BR Nitrile rubber, NBR
- Penetration time of glove material
- 0,3 mm

Penetration time 60 min.

- 0,11 mm
- Penetration time 10 min.
- · Eye/face protection Safety glasses

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and ch	nemical properties
· General Information	
· Colour:	Yellow
· Odour:	Weak, characteristic
• Odour threshold:	Not determined.
Melting point/freezing point:	undetermined
· Boiling point or initial boiling point and boiling	
range	100 °C (7732-18-5 water, distilled, conductivity or of
	similarpurity)
· Flammability	Not applicable.
· Lower and upper explosion limit	
· Lower:	3.5 Vol %
· Upper:	15.0 Vol %
· Flash point:	Not applicable

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Auto-ignition temperature:	Product is not selfigniting.
Decomposition temperature:	Not determined.
pH at 20 °C	3
Viscosity:	
Kinematic viscosity	Not determined.
dynamic at 20 °C:	1,200 mPas
Solubility	
Water:	Fully miscible
Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure at 20 °C:	23 hPa (7732-18-5 water, distilled, conductivity or o
	similarpurity)
Density and/or relative density	
Density at 20 °C:	$l g/cm^3$
Relative density	Not determined.
Vapour density	Not determined.
9.2 Other information	
Appearance:	
Form:	Fluid
Important information on protection of health a	
environment, and on safety.	
Ignition temperature:	425 °C
Explosive properties:	Product is not explosive. However, formation of
1 · · · · · · · · · · · · · · · · · · ·	explosive air/vapour mixtures are possible.
Change in condition	
Evaporation rate	Not determined.
Information with regard to physical hazard clas	ises
Explosives	Void
Flammable gases	Void
Aerosols	Void
Oxidising gases	Void
Gases under pressure	Void
Flammable liquids	Void
Flammable solids	Void
Self-reactive substances and mixtures	Void
Pyrophoric liquids	Void
Pyrophoric solids	Void
Self-heating substances and mixtures	Void
Substances and mixtures, which emit flammable	
gases in contact with water	Void
Oxidising liquids	Void
	Void
	VOIA
Oxidising solids	
	Void Void Void

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

· 10.2 Chemical stability

- *Thermal decomposition / conditions to be avoided:* No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions Exothermic polymerization
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials:

Oxidation agent.

Acids

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Alkali

Ethanol

In presence of radical formers (e. g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.

· 10.6 Hazardous decomposition products: No dangerous decomposition products known

SECTION 11: Toxicological information

- 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Based on available data, the classification criteria are not met.
- · LD/LC50 values relevant for classification:
 - 10470 mg/kg rat OECD 401 LD-50 oral **OECD 402**
 - LC-50 inhalativ 117 mg/l rat

· Skin corrosion/irritation Drying out of skin possible

- Serious eye damage/irritation
- Causes serious eye irritation.

• Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- *Reproductive toxicity Based on available data, the classification criteria are not met.*
- STOT-single exposure
- May cause respiratory irritation.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.
- · 11.2 Information on other hazards
- · Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

· 12.1 Toxicity

- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- Other information: The product is biodegradable.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- 12.6 Endocrine disrupting properties For information on endocrine disrupting properties see section 11.
- · 12.7 Other adverse effects
- Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation
- Must be specially treated adhering to official regulations.

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

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· Uncleaned packaging:

• **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport informat	ion	
· 14.1 UN number or ID number · ADR, IMDG, IATA	Void	
· 14.2 UN proper shipping name · ADR, IMDG, IATA	Void	
· 14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	Void	
· 14.4 Packing group · ADR, IMDG, IATA	Void	
· 14.5 Environmental hazards: · Marine pollutant:	No	
· 14.6 Special precautions for user	Not applicable.	
• 14.7 Maritime transport in bulk according instruments	g to IMO Not applicable.	
· UN "Model Regulation":	Void	

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

· National regulations

• Technical instructions (air):

Class	Share in %
NK	10-25

• Waterhazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water.

• 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Relevant phrases H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

· Department issuing SDS: Micerium S.p.a.

· Contact: Dr. Eugenio Miceli

· Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

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ICAO: International Civil Aviation Organisation
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the
International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
* * Data compared to the previous version altered.