SCHEDA DI DATI DI SICUREZZA

1. PREPARATION AND COMPANY IDENTIFICATION

1.1. Product identification

a) Cements without antibiotic:

RALLY HV **BONE CEMENT 40 GRAMS**
RALLY MV **BONE CEMENT 40 GRAMS**

b) Cements with antibiotic *(gentamicin):*

RALLY HV AB **BONE CEMENT 40 GRAMS**
RALLY MV AB **BONE CEMENT 40 GRAMS**
RALLY HV AB **ALL IN ONE SYSTEM 70 GRAMS**
RALLY MV AB **ALL IN ONE SYSTEM 70 GRAMS**

1.2. Preparation utilization: Bone cement for medical applications

1.3. Company identification:

TECRES SpA

Via Andrea Doria, 6
37066 Sommacampagna (VR) - Italy
Tel. +39 045 9217 311
Fax +39 045 9217 330
e-mail: valeria.pasotto@tecres.it

1.4.Emergency telephone: +039 02 66101029 (24 ore su 24, Centro Antiveleni Niguarda Cà Granda - Milano)

2. HAZARD IDENTIFICATION

2.1 Mixture classification

2.1.1 Classification according to Regulation (EC) No. 1272/2008 [CLP Regulation]

SOLID COMPONENT	Hazard classes and categories	Warnings
Polymethyl methacrylate	Non-hazardous	-
Barium sulphate	Non-hazardous	-
Gentamicin Sulphate *(only cements with gentamicin)*	Airway sensitization (Category 1) Skin sensitization (Category 1)	H334 H317
LIQUIDCOMPONENT		
Methyl methacrylate	Flammable liquids (Category 2) Skin irritation (Category 2) Skin sensitization (Category 1) Specific toxicity for target organs - single exposure (Category 3)	H225 H315 H317 H335
N,N-dimethyl-p-toluidine	Specific toxicity for target organs - repeated exposure (Category 2) Toxicity for the aquatic environment (Category 3) Acute toxicity, Inhalation (Category 3) Acute toxicity, Dermal (Category 3) Acute toxicity, Oral (Category 3)	H373 H412 H311 H331 H301

2.1.2 Classification according to Directives 67/548/EEC or 1999/45/EC

SOLID COMPONENT		Risk Phrases
Polymethyl methacrylate	Non-hazardous	-
Barium Sulphate	Non-hazardous	-
Gentamicin Sulphate *(only cements with gentamicin)*	Sensitization by inhalation and skin contact.	R42/43
LIQUID COMPONENT		
Methyl methacrylate	Easily flammable, irritant	R11, R37/38, R43
N,N-dimethyl-p-toluidine	Toxic by inhalation, skin contact and ingestion. Danger of cumulative effects. Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	R23/24/25 R33 R52/53

Notes: Carcinogenicity, teratogenicity, mutagenicity, chronic toxicity on the reproductive system and synergistic properties are not known.

3. COMPOSITION/INFORMATION ON THE INGREDIENTS

General description of the components: powder mainly composed of methyl methacrylate polymers and liquid mainly composed of methyl methacrylate.

Constituent chemical name	***EC No.***	***CAS No.***	***EC INDEX NO.***	***Concentration (%)***
SOLID COMPONENT				
Polymethyl methacrylate	-	25034-86-0 9011-14-7	-	~ 65.5 – 97.0
Barium sulphate	231-784-4	7727-43-7	-	~ 9.0 – 28.5
Gentamicin sulphate (only cements with gentamicin)	215-778-9	1405-41-0	-	~ 4.22
LIQUID COMPONENT				
Methyl methacrylate	201-297-1	80-62-6	607-035-00-6	~ 98.2 - 99.1
N,N-dimethyl-p-toluidine	202-805-4	99-97-8	612-056-00-9	~ 0.45 - 1.8

4. PROVIDING FIRST AID

4.1 General information
In case of exposure or feeling unwell, seek medical advice. In case of fainting, roll casualty onto their side in a stable position and seek medical advice. Never give anything to eat or drink to someone who is unconscious or has cramps. Take off dirty or impregnated clothes. Do not leave the casualty unattended.

4.2 In case of inhalation
Remove casualty to fresh air. If breathing is irregular or interrupted, administer artificial respiration.

4.3 In case of skin contact
Take off contaminated clothing and wash the skin with plenty of soap and water. In case of skin reactions, seek medical advice.

4.4 In case of contact with eyes
Immediately rinse eyes with plenty of water. Take out contact lenses if easy to do.

4.5 In case of ingestion
Rinse the mouth with water if the casualty is conscious. Seek medical advice. Do not induce vomiting and do not give the casualty anything to drink or eat.

4.6 Self-protection
First aid rescuer: Make sure that you protect yourself!

Solid component:	Keep persons that have been subjected to excessive or prolonged exposure to the powder with antibiotic under medical observation.
Liquid component:	Keep under medical observation, as it contains N,N-dimethyl-p-toluidine.

5. FIRE-FIGHTING MEASURES

5.1 Fire-extinguishing means
Suitable fire-extinguishing means
Use Class B fire-extinguishing means: atomized water, carbon dioxide or dry powder.
5.2 Fire-extinguishing means not to be used for safety reasons
N.A.
5.3 Special exposure hazards arising from the substance, products of combustion or the gases produced
Avoid breathing in the combustion fumes as they may be toxic following a fire.
Solid component: Combustible but not easily ignitable. Combustion or thermal decomposition releases irritating, toxic and flammable vapours. This product may form flammable dust clouds at high temperatures. The minimum ignition temperature of a dust cloud is about 480°C.
Liquid component: Easily flammable liquid and vapours. May polymerize producing heat.
5.4 Special protection devices for fire-fighting staff
Protective clothing complete with breathing apparatus.

6. MEASURES IN CASE OF ACCIDENTAL SPILLAGE (also see sections 8 and 13)

6.1 Personal precautions, protection devices and emergency procedures
Avoid dust development. Do not breathe in dust. Provide for sufficient ventilation. Eliminate any source of ignition: avoid sources of sparks and ignition. Avoid contact with the skin, eyes and clothes.
6.2 Precautions for the environment
Avoid spilling the product into the sewerage and aquifers.
6.3 Methods and material for containment and decontamination
Sweep and shovel. Dry with inert adsorbent material, collect in containers and have it disposed of by an authorised company. Wash the contaminated place with water after having collected all the material.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling
Avoid inhaling vapours. Avoid contact with the eyes, skin and clothes. Avoid prolonged exposure. Adopt adequate ventilation in places where dust develops.
7.2 Conditions for safe storage, including any incompatibility
Keep hermetically sealed. Store in a cool and well-ventilated place away from any source of heat, sparks and flames.
7.3 Specific final uses
No data available

8. PERSONAL PROTECTION/EXPOSURE CONTROL

8.1 Control parameters
Exposure limit values
Solid component: Does not contain substances with an occupational exposure limit value.
Liquid component: TLV-TWA = 50 ppm
TLV-STEL = 100 ppm
8.2 Exposure control
In case of handling: wear gloves and protective goggles.
Solid component: should the operating procedures to limit exposure not be adequate, wear airway protection devices (dust mask with filters type P1).
Componente liquido: avoid inhaling liquid vapours, if necessary using full-face masks with combined filters type ABEK.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on the basic physical and chemical properties

Solid component (polymer):

a)	Appearance	Physical state: volatile powder Colour: white
b)	Odour	Odourless
c)	Olfactory threshold	No data avalable
d)	pH	No data avalable
e)	Melting point / freezing point	No data avalable
f)	Initial boiling point and boiling range	No data avalable
g)	Flash point	> 250°C
h)	Evaporation rate	No data avalable
i)	Flammability (solids, gases)	No data avalable
j)	Upper/lower flammability or explosive limits	No data avalable
k)	Vapour pressure	No data avalable
l)	Vapour density	No data avalable
m)	Relative density	1.2 g/cm^3
n)	IWater solubility	No data avalable
o)	Partition coefficient: n-octanol/water	No data avalable
p)	Self-ignition temperature	304°C
q)	Decomposition temperature	No data avalable
r)	Viscosity	No data avalable
s)	Explosive properties	No data avalable
t)	Oxidizing properties	No data avalable
u)	Solubility in water	Insoluble (cements without antibiotic), Gentamicin sulphate present in the cements with antibiotic are soluble

Liquid Component (methyl methacrylate):

a)	Appearance	Physical state: liquid Colour: colourless
b)	Odourless	Characteristic pungent odour
c)	Olfactory threshold	No data avalable
d)	pH	No data avalable
e)	Melting point / freezing point	- 48°C
f)	Initial boiling point and boiling range	100°C
g)	Flash point	9°C – closed container
h)	Evaporation rate	No data avalable
i)	Flammability (solids, gases)	No data available
j)	Upper/lower flammability or explosive limits	Upper explosive limit: 12.5% Lower explosive limit: 2.12%
k)	Vapour pressure	51,3 hPa a 25°C

l)	Vapour density	3,46
m)	Relative density	0,936 g/cm^3 a 25°C
n)	Water solubility	15 g/l
o)	Partition coefficient: n-octanol/water	Log pow 1,38
p)	Self-ignition temperature	No data available
q)	Decomposition temperature	No data available
r)	Viscosity	No data available
s)	Explosive properties	No data available
t)	Oxidizing properties	No data available
u)	Surface tension	28 mN/m A 20°C
v)	Relative vapour density	3,46 – (Air = 1.0)

Note: information not shown is not applicable

9.2 Other safety information
No data available

10. STABILITY AND REACTIVITY

10.1 Reactivity
No data available.

10.2 Chemical stability
The liquid component is stable in the recommended storage conditions. It polymerizes with development of heat, increasing the pressure which may burst the container. Avoid contact with incompatible materials.

10.3 Possibility of dangerous reactions
No data available.

10.4 Conditions to avoid
The liquid component may polymerize if exposed to: heat, flames and sparks, extreme temperatures and direct sunlight, humidity and strong light, in particular fluorescent or UV.

10.5 Incompatible materials
Oxidizing agents Peroxides, ammines, bases, strong acids, reducing agents and halogens.

10.6 Dangerous decomposition products
No data available.

10.7 Materials to avoid
The liquid component may polymerize: avoid organic peroxides, catalysts, free radical generators and multivalent metal oxides, especially if wet.
The volatile and flammable liquid component slowly attacks rubber.

10.8 Decomposition products
Carbon monoxide, carbon dioxide.
In case of fire: see section 5

11. TOXICOLOGICAL INFORMATION

SOLID COMPONENT

Acute toxicity	Gentamicin: DL50 oral - rat > 5000 mg/kg Observations: sleepy behaviour (generic depressive activity)
Corrosion/skin irritation	No data available
Serious eye injury/irritation	No data available
Respiratory or skin sensitization	No data available
Mutagenicity of germinal cells	Mouse - micronucleus test
Carcinogenicity	Carcinogenicity - rat - implant Oncogenicity: tumours at the application site Carcinogenicity - rat - intrapleural Oncogenicity: dubious oncogenic agent according to RTECS Lungs, chest or respiration: tumours IARC: no component present at levels ≥ 0.1% is identified as carcinogenic
Reproductive toxicity	No data available
Specific toxicity for target organs - single exposure	No data available
Specific toxicity for target organs - repeated exposure	No data available
Hazard in case of inhalation	No data available
Potential health consequences	**- Inhalation:** May be harmful if inhaled. May cause airway irritation **- Ingestion:** May be hazardous if swallowed **- Skin:** May be harmful if absorbed through the skin. May cause skin irritation. **- Eyes:** May cause eye irritation.
Signs and symptoms of exposure	The chemical, physical and toxicological properties have not been subjected to in-depth studies.
Additional information	RTECS: Polymethyl methacrylate TR0400000 RTECS: Barium sulphate - No data available RTECS: Gentamicin sulphate LY2625000

LIQUID COMPONENT

Acute toxicity	Methyl methacrylate: DL50 oral - rat - 7872 mg/kg Observations: muscular weakness N,N-dimethyl-p-toluidine: CL50 inhalation- rat - 4h – 1400 mg/kg DL intraperitoneal - mouse - 212 mg/kg
Corrosion/skin irritation	No data available
Serious eye injury/irritation	No data available
Respiratory or skin sensitization	May cause respiratory and skin allergic reactions
Mutagenicity of germinal cells	In vivo genotoxicity - rat - intraperitoneal: DNA damage In vivo genotoxicity - mouse - intraperitoneal: DNA damage
Carcinogenicity	IARC: no component present at levels ≥ 0.1% is identified as carcinogenic
Reproductive toxicity	No data available
Specific toxicity for target organs - single exposure	May irritate the airways
Specific toxicity for target organs - repeated exposure	No data available

Hazard in case of inhalation	nessun dato disponibile
Potential health consequences	**- Inhalation:** May be harmful if inhaled. May cause airway irritation. **- Ingestion:** May be hazardous if swallowed **- Skin:** May be harmful if absorbed through the skin. May cause skin irritation. **- Eyes:** May cause eye irritation.
Signs and symptoms of exposure	The chemical, physical and toxicological properties have not been subjected to in-depth studies.
Additional information	RTECS: Methyl methacrylate OZ5075000 RTECS: N,N-dimethyl-p-toluidine XU5803000

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Solid component: no data available

Liquid component:

Toxicity for fish: CL50 Pimephales promelas (American chub) - 125.5 - 275 mg/l - 96h

Toxicity for daphnia CE50 Daphnia magna (large water flee) - 720 mg/l and for other aquatic invertebrates

Toxicity for algae: CE50 pseudokirchneriella subcapitata (chloroforic algae) - 170 mg/l - 96h

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulation power

No data available

12.4 Mobility in the ground

No data available

12.5 PBT and vPvB evaluation results

No data available

12.6 Other adverse effects

No data available

13. CONSIDERATIONS ON DISPOSAL

13.1 Waste treatment methods

Products

Mix the powder and liquid of a package in order to obtain a non-hazardous product and/or dispose of the product in accordance with the local regulations in force.

Contaminated containers

Dispose of as contaminated container

14. INFORMATION ON TRANSPORT

14.1 UN number:
Solid component: Non-hazardous
Liquid component:
ADR/RID: 1247 (liquid component)
IMDG: 1247 *(liquid component)*
IATA: 1247 *(liquid component)*

14.2 UN shipping regulations
Solid component: Non-hazardous
Liquid component:

ADR/RID: Methyl methacrylate monomer stabilized (liquid component)

IMDG: Methyl methacrylate monomer stabilized (liquid component)

IATA: Methyl methacrylate monomer stabilized (liquid component)

14.3 Hazard classes for materials in transport
Solid component: Non-hazardous
Liquid component:

ADR/RID: 3 IMDG: 3 IATA: 3

14.4 Packaging unit
Solid component: Non-hazardous
Liquid component:

ADR/RID: II *(liquid component)* IMDG: II *(liquid component)* IATA: II *(iquid component)*

14.5 Environmental hazards

Solid component:	ADR/RID: no	IMDG marine pollutant: no	IATA: no
Liquid component:	ADR/RID: no	IMDG marine pollutant: no	IATA: no

14.6 Special precautions for users
no data available

15.INFORMATION ON REGULATIONS

This safety data sheet is in compliance with the requirements of Regulation (EC) No. 1907/2006

15.1 Regulations and legislation on health, safety and the environment specifically for the mixture
no data available
15.2 Chemical safety evaluation
No chemical safety evaluation was conducted for this mixture.

16. OTHER INFORMATION

Additional information

The information contained in this safety data sheet is deemed correct; nonetheless, itmay not be exhaustive and should therefore be considered purely by way of indication. Tecres S.p.A. cannot be held responsible for any harm deriving from use of or contact with the product described in this safety data sheet.

Changes compared to the previous edition: issuance.