Ciment Cerafixgenta HV

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (amended by Regulation (EU) No. 2017/776)

Version:1 Version date:18/02/2020 Language:EN

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

1.1. Product identifier

Trade name/designation : Ciment Cerafixgenta HV

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Surgical acrylic cement. High viscosity - Radio-opaque.
CERAFIXGENTA HV® is specially indicated in:
- interventions in patients at risk (altered general condition, undernourished, diabetics, pulmonary or urinary tract infections, bone fragility),
- reoperations for hip sepsis, sepsis of other joints developed on prostheses.

Uses advised against : No data available.

1.3. Details of the supplier of the safety data sheet

Supplier : Name: CERAVER – Les Laboratoires Ostéal Médical
Street: 69 rue de la Belle Etoile
Postal code/City: 95957 Roissy CDG Cedex
Country: France
Telephone: (+33) 1 48 63 88 63
Telefax: (+33) 1 48 63 88 99
E-mail: contact@ceraver.com

1.4. Emergency Telephone Number

United Kingdom: In England and Wales: dial 111 (NHS 111), In Scotland: dial 111 (NHS 24), In Northern Ireland: Contact your local GP or pharmacist during normal hours. During GP Out-of-Hours (www.gpoutofhours.hscni.net/): Belfast HSC Trust, (North & West) 028 9074 4447, (South & East) 028 9079 6220 South Eastern HSC Trust, (North Down & Ards) 028 9182 2344, (Lisburn & Downpatrick) 028 9260 2204, Dalriada Urgent Care (Northern Trust area) 028 2566 3500, Southern HSC Trust 028 3839 9201, Western Urgent Care 028 7186 5195

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

	Classification	Hazard statements (H)	
	Org. Perox. B	H241	Heating may cause a fire or explosion.
	Skin Irrit. 2	H315	Causes skin irritation.
	Skin Sens. 1	H317	May cause an allergic skin reaction.
	Resp. Sens. 1	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
	STOT SE 3	H335	May cause respiratory irritation

2.2. Label elements

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

Hazard pictograms 

Signal word Danger

Product identifiers -

Hazard Statements	H241 - Heating may cause a fire or explosion. H315 - Causes skin irritation. H317 - May cause an allergic skin reaction. H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled. H335 - May cause respiratory irritation
Supplemental Hazard information (EU)	-
Precautionary Statements - General	-
Precautionary Statements - Prevention	P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P234 - Keep only in original container. P261 - Avoid breathing dust/fume/gas/mist/vapours/spray. P280 - Wear protective gloves/protective clothing/eye protection/face protection.
Precautionary Statements - Response	P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER/doctor/… P370+P380+P375 - In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.
Precautionary Statements - Storage	-
Precautionary Statements - Disposal	-

2.3. Other hazards

Not available

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance	C (%)	Classification	Specific concentration limits	Note
methyl methacrylate CAS N°:80-62-6 EC N°:201-297-1 IDX N°:607-035-00-6	C≤ 23.43792%	H225: Highly flammable liquid and vapour. H315: Causes skin irritation. H317: May cause an allergic skin reaction. H335: May cause respiratory irritation	-	[1]
butyl methacrylate CAS N°:97-88-1 EC N°:202-615-1 IDX N°:607-033-00-5	C≤ 3.60732%	H226: Flammable liquid and vapour. H315: Causes skin irritation. H317: May cause an allergic skin reaction. H319: Causes serious eye irritation H335: May cause respiratory irritation	-	-
Gentamicin, sulfate (salt) CAS N°:1405-41-0 EC N°:215-778-9 IDX N°:	C≤ 2.0996%	H317: May cause an allergic skin reaction. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.	-	-
dibenzoyl peroxide CAS N°:94-36-0 EC N°:202-327-6 IDX N°:617-008-00-0	C< 1.192428%	H241: Heating may cause a fire or explosion. H317: May cause an allergic skin reaction. H319: Causes serious eye irritation	-	-

[1] Substance for which maximum workplace exposure limits are available.

3.2. Mixtures

The mixture does not contain any substances classified as Substances of Very High Concern (SVHC) by the European CHemicals Agency (ECHA) under article 57 of REACH: http://echa.europa.eu/fr/candidate-list-table.

3.3. Remark

Text phrases and H- EUH-: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information	:	In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Keep affected person warm, still and covered. Do not leave affected person unattended.
Following inhalation	:	Remove person to fresh air and keep comfortable for breathing. If the victim is unconscious but breathing normally, place her in recovery position and seek medical advice. In case of allergic symptoms, especially in the breathing area, seek medical advice immediately. No resuscitation mouth-to-mouth or mouth-to-nose. Ambu use a mask or respirator. If breathing is irregular or stopped, administer artificial respiration.
Following skin contact	:	Change contaminated, saturated clothing. Take off contaminated clothing. In case of skin irritation, consult a physician. After contact with skin, wash immediately with plenty of water and soap.
Following eye contact	:	In case of eye irritation consult an ophthalmologist. Rinse immediately carefully and thoroughly with eye-bath or water. Remove contact lenses, if present and easy to do. Continue rinsing.
Following ingestion	:	Never give anything by mouth to an unconscious person or a person with cramps. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
Self-protection of the first aider	:	First aider: Pay attention to self-protection!.

4.2. Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

4.3. Indication of any immediate medical attention and special treatment needed

Notes for the doctor	:	Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	:	Foam. Extinguishing powder. Carbon dioxide (CO2). Sand.
Unsuitable extinguishing media	:	Strong water jet.

5.2. Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

5.4. Additional information

Do not inhale vapors and fumes. Co-ordinate fire-fighting measures to the fire surroundings. Move undamaged containers from immediate hazard area if it can be done safely. Use caution when applying carbon dioxide in confined spaces. carbon dioxide can displace oxygen. Use water spray jet to protect personnel and to cool endangered containers. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protection equipment. Remove persons to safety. Provide adequate ventilation. Use appropriate respiratory protection.

6.2. Environmental precautions

Ensure that waste is collected and contained. In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

6.3. Methods and material for containment and cleaning up

Treat the recovered material as prescribed in the section on waste disposal. Collect in closed and suitable containers for disposal. Clean contaminated objects and areas thoroughly observing environmental regulations. Ventilate affected area.

6.4. Reference to other sections

Safe handling: see section 7. Disposal: see section 13. Personal protection equipment: see section 8.

6.5. Additional information

Not available

SECTION 7: Handling and Storage

7.1. Precautions for safe handling

Avoid exposure - obtain special instructions before use. Use only outdoors or in a well-ventilated area.

PROTECTIVE MEASURES

Avoid contact with skin, eyes and clothes.
Wear personal protective clothing (see section 8).
Use only in well-ventilated areas.
If local exhaust ventilation is not possible or not enough, the entire work area must be ventilated by technical means.
Provide adequate ventilation as well as local exhaustion at critical locations.
Dust should be exhausted directly at the point of origin.
Avoid breathing dust.

Advices on general occupational hygiene

Wash hands before breaks and after work.
Remove contaminated, saturated clothing immediately.
Wash contaminated clothing before reuse.
Street clothing should be stored seperately from work clothing.
Work in well ventilated zones or use proper respiratory protection.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry, cool, and well-ventilated place. Keep container in upright position in order to prevent leakage.

Requirements for storage rooms and vessels

Protect from sunlight.
Ensure adequate ventilation of the storage area.
Keep only in original container.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Store locked up.

Advice on joint storage

Keep away from food, drink and animal feedingstuffs.
Store away from other materials.
Keep away from clothing and other combustible materials.
Keep only in the original container in a cool, well-ventilated place, away from highly flammable substances.

7.3. Specific end uses

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

Substance	Value	Unit	Type
methyl methacrylate CAS: 80-62-6 (EU)	50	ppm	Exposure limit (8 hours)
methyl methacrylate CAS: 80-62-6 (EU)	100	ppm	Exposure limit (15 minutes)
methyl methacrylate CAS: 80-62-6 (IE)	50	ppm	Exposure limit (8 hours)
methyl methacrylate CAS: 80-62-6 (IE)	100	ppm	Exposure limit (15 minutes)
methyl methacrylate CAS: 80-62-6 (GB)	208	mg/m³	Exposure limit (8 hours)

methyl methacrylate CAS: 80-62-6 (GB)	50	ppm	Exposure limit (8 hours)
methyl methacrylate CAS: 80-62-6 (GB)	416	mg/m³	Exposure limit (15 minutes)
methyl methacrylate CAS: 80-62-6 (GB)	100	ppm	Exposure limit (15 minutes)

Not available

8.2. Exposure controls

Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment. Provide adequate ventilation as well as local exhaustion at critical locations.

Personal protection equipment

Eye/face protection	:	Suitable eye protection: No data available
Skin protection	:	Hand protection: Wear protective gloves. Hand protection: NBR (nitrile rubber) Hand protection: Do not wear gloves near machines and rotating tools. Hand protection: Use gloves only once. Hand protection: When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. Hand protection: The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. Hand protection: For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. Hand protection: Breakthrough times and swelling properties of the material must be taken into consideration.Body protection: Lab coat.
Respiratory protection	:	Respiratory protection necessary at: If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn.Suitable respiratory protection apparatus: Wear respiratory protection.Remark: The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used. Remark: Observe the wear time limits as specified by the manufacturer. Remark: Use only respiratory protection equipment with CE-symbol including four digit test number.

8.3. Additional information

Not available

SECTION 9: Physical and chemical Properties

9.1. Information on basic physical and chemical properties

Physical state:	Solid
Colour:	Yellowish
Odour:	Not available
Odour threshold:	Not available
pH:	Not available
Melting point/freezing point:	Not available
Initial boiling point and boiling range:	Not available
Flash point:	Not available
Evaporation rate:	Not available
Flammability:	Not available
Upper/lower flammability or explosive limits:	Not available
Vapour pressure:	Not available

Vapour density:	Not available
Relative density:	Not available
Solubility(ies):	Not available
Partition coefficient: n-octanol/water (Log KOC):	Not available
Auto-ignition temperature:	Not available
Decomposition temperature:	Not available
Viscosity:	Not available
Explosive properties:	Not available
Oxidising properties:	Not available

9.2. Other safety information

Not available

SECTION 10: Stability and Reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Not available

10.3. Possibility of hazardous reactions

Not available

10.4. Conditions to avoid

No data available.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

Not available

10.7. Additional information

Not available

SECTION 11: Toxicological information

11.1. Acute oral toxicity

Data for mixture

Not available

Substances

dibenzoyl peroxide (CAS: 94-36-0)

Species	:	Rat
Sex	:	Male
Guideline	:	Not available

Subendpoint	Operator	Value	Unit
LD50:	>	5.000	mg/kg bw

Conclusion : Not available

butyl methacrylate (CAS: 97-88-1)

Species	:	Rat
Sex	:	Not available
Guideline	:	OECD 401, (study carried out by us)

Subendpoint	Operator	Value	Unit
LD50:	>	2.000	mg/kg bw

Conclusion : Not available

Gentamicin, sulfate (salt) (CAS: 1405-41-0)

Species : Mouse
Sex : Not available
Guideline : Not available

Subendpoint	Operator	Value	Unit
LD50:	=	11269	mg/kg bw

Conclusion : Not available

Species : Rat
Sex : Not available
Guideline : Not available

Subendpoint	Operator	Value	Unit
LD50:	>	5000	mg/kg bw

Conclusion : Not available

methyl methacrylate (CAS: 80-62-6)

Species : Rat
Sex : Not available
Guideline : OECD 401

Subendpoint	Operator	Value	Unit
LD50:	>	5.000	mg/kg bw

Conclusion : Not available

11.2. Acute skin toxicity

Data for mixture

Species : Rabbit (oryctolagus cuniculus).
Breed: New Zealand White.
Source: Charles River Laborotories France (B.P. 109, 69592 l'Arbresle).
Age: Young adults.
Number of animals: 2.
Identification method: A unique identification was marked in the ear of each animal

Sex : Males

Guideline : The study was conducted according to the ISO 10993 Standard : Biological evaluation of medical devices.
Part 2 (2006): Animal welfare requirements.
Part 10 (2002) and Part 10/A1 (2006): Test for Irritation and Delayed Type Hypersensitivity.
Part 12 (2007): Test article preparation and reference materials.

Exposure duration/value : 34
Exposure duration/unit : days

Subendpoint	Operator	Value	Unit
Body weight range	-	2.7 et 2.9 kg at the beginning of the treatment	-

Conclusion : The 0.9% NaCl and sesame oil extracts from the test article met the requirements of the intracutaneous injection test in rabbit according to the procedure described in the ISO 10993-10 standard.

Substances

butyl methacrylate (CAS: 97-88-1)

Species : Rabbit

Sex : Not available
Guideline : OECD 402, (study carried out by us)
Exposure duration/value : Not available
Exposure duration/unit : Not available

Subendpoint	Operator	Value	Unit
LD50:	>	2.000	mg/kg bw

Conclusion : Not available

methyl methacrylate (CAS: 80-62-6)
Species : Rabbit
Sex : Not available
Guideline : Not available
Exposure duration/value : Not available
Exposure duration/unit : Not available

Subendpoint	Operator	Value	Unit
LD50:	>	5.000	mg/kg bw

Conclusion : Not available

11.3. Acute inhalation toxicity

Data for mixture
Not available
Substances
dibenzoyl peroxide (CAS: 94-36-0)
Species : Rat
Sex : Male
Guideline : OECD Test Guideline 403
Route of administration : Not available
Exposure duration/value : 4
Exposure duration/unit : h

Subendpoint	Results/Sex	Operator	Value	Unit
LC50:	-	=	24,3	mg/L

Conclusion : Not available

butyl methacrylate (CAS: 97-88-1)
Species : Rat
Sex : Not available
Guideline : TSCA Guideline
Route of administration : Not available
Exposure duration/value : Not available
Exposure duration/unit : Not available

Subendpoint	Results/Sex	Operator	Value	Unit
LC50:	-	=	29	mg/L

Conclusion : Not available

methyl methacrylate (CAS: 80-62-6)
Species : Rat
Sex : Not available
Guideline : Not available
Route of administration : Not available

Exposure duration/value : Not available
Exposure duration/unit : Not available

Subendpoint	Results/Sex	Operator	Value	Unit
LC50:	-	=	29,8	mg/L

Conclusion : Not available

11.4. Skin corrosion

Data for mixture

Not available

Substances

dibenzoyl peroxide (CAS: 94-36-0)

Test type : Not available
Species : Rabbit
Sex : Not available
Guideline : OECD Test Guideline 404
Exposure duration/value : Not available
Exposure duration/unit : Not available

Subendpoint	Basis	Time Point	Reversibility
-	-	-	-

Conclusion : No skin irritation.

butyl methacrylate (CAS: 97-88-1)

Test type : Not available
Species : Rabbit
Sex : Not available
Guideline : Not available
Exposure duration/value : Not available
Exposure duration/unit : Not available

Subendpoint	Basis	Time Point	Reversibility
-	-	-	-

Conclusion : moderately irritating. Frequent or prolonged contact may cause irritation. Skin irritant Category 2 (UN-GHS)

Gentamicin, sulfate (salt) (CAS: 1405-41-0)

Test type : Not available
Species : Not available
Sex : Not available
Guideline : Not available
Exposure duration/value : Not available
Exposure duration/unit : Not available

Subendpoint	Basis	Time Point	Reversibility
-	-	-	-

Conclusion : No irritant effect.

methyl methacrylate (CAS: 80-62-6)

Test type : Not available
Species : Rabbit
Sex : Not available
Guideline : Not available

Exposure duration/value : Not available
Exposure duration/unit : Not available

Subendpoint	Basis	Time Point	Reversibility
-	-	-	-

Conclusion : non-irritant - slightly irritating. Frequent or prolonged contact may cause irritation. Skin irritant Category 2 (UN-GHS).

11.5. Eye damage

Data for mixture

Not available

Substances

dibenzoyl peroxide (CAS: 94-36-0)

Test type : Not available
Species : Rabbit
Sex : Not available
Guideline : OECD Test Guideline 405
Type of method : Not available
Concentration : Not available

Subendpoint	Basis	Time Point	Reversibility
-	-	-	-

Conclusion : Irritating to eyes, reversible in 21 day.

butyl methacrylate (CAS: 97-88-1)

Test type : Not available
Species : Rabbit
Sex : Not available
Guideline : Not available
Type of method : Not available
Concentration : Not available

Subendpoint	Basis	Time Point	Reversibility
-	-	-	-

Conclusion : non-irritating - slightly irritating

Gentamicin, sulfate (salt) (CAS: 1405-41-0)

Test type : Not available
Species : Not available
Sex : Not available
Guideline : Not available
Type of method : Not available
Concentration : Not available

Subendpoint	Basis	Time Point	Reversibility
-	-	-	-

Conclusion : No irritant effect.

methyl methacrylate (CAS: 80-62-6)

Test type : Not available
Species : Rabbit
Sex : Not available
Guideline : Not available

Type of method : Not available
Concentration : Not available

Subendpoint	Basis	Time Point	Reversibility
-	-	-	-

Conclusion : non-irritating - slightly irritating

11.6. Skin sensitisation

Data for mixture

Species : Guinea pig (Cavia porcellus).
Race: Dunkin Hartley.
Source: Charles River Laboratories France (B.P. 109, 69592 l'Arbresle).
Age: Young adults.
Number of animals: 48.
Identification method: Ear tag

Sex : Males

Guideline : The study was conducted according to the ISO 10993 Standard : Biological evaluation of medical devices.
Part 2 (2006): Animal welfare requirements.
Part 10 (2002) and Part 10/A1 (2006): Test for Irritation and Delayed Type Hypersensitivity.
Part 12 (2007): Test article preparation and reference materials.

Exposure duration/value : 6
Exposure duration/unit : days
Concentration : Not available

Subendpoint	Value	Unit
Body weight range	346 grams to 420 grams at assay initiation (for the naïve control guinea pigs used for the second challenge)	-
Body weight range	300 grams to 352 grams at assay initiation (main test)	-

Conclusion : Under the conditions of this study after the second challenge, the topical application of the 0.9% NaCl extract evaluated at a concentration of 100%, according to the ISO 10993-10 standard, did not induce delayed sensitization in the guinea pig (grade 0). The topical application of the sesame oil extract evaluated at a concentration of 100%, according to the ISO 10993-10 standard, did not induce delayed sensitization in the guinia pig (grade 0). Based on these results, the test article was thus not considered a sensitizer in the guinea pig maximization model.
The intradermal injection of the 0.9% NaCl extract evaluated at a concentration of 100%, supplement to the ISO 10993-10 standard, did not induce delayed sensitization in the guinea pig (grade 0). Based on this result, the test article was thus not considered a sensitizer in the guinea pig maximization model.

Substances

dibenzoyl peroxide (CAS: 94-36-0)

Species : Mouse
Sex : Not available
Guideline : OECD Test Guideline 429
Exposure duration/value : Not available
Exposure duration/unit : Not available
Concentration : Not available

Subendpoint	Value	Unit
-	-	-

Conclusion : Result: May cause sensitization by skin contact.

butyl methacrylate (CAS: 97-88-1)

Species	:	Not available
Sex	:	Not available
Guideline	:	Not available
Exposure duration/value	:	Not available
Exposure duration/unit	:	Not available
Concentration	:	Not available

Subendpoint	Value	Unit
-	-	-

Conclusion : In animal experiments, the substance reveals weakly marked or absent sensitization properties. In humans, mention is made of an sensitizing effect of the substance. skin sensitization Category 1B (UN-GHS)

Gentamicin, sulfate (salt) (CAS: 1405-41-0)

Species	:	Not available
Sex	:	Not available
Guideline	:	Not available
Exposure duration/value	:	Not available
Exposure duration/unit	:	Not available
Concentration	:	Not available

Subendpoint	Value	Unit
-	-	-

Conclusion : No sensitizing effects known

methyl methacrylate (CAS: 80-62-6)

Species	:	Mouse
Sex	:	Not available
Guideline	:	Not available
Exposure duration/value	:	Not available
Exposure duration/unit	:	Not available
Concentration	:	Not available

Subendpoint	Value	Unit
-	-	-

Conclusion : LLNA (Local Lymph Node Assay), (study carried out by us). man, In humans, allergic reactions of various incidence have been observed (symptoms: headache, eye irritation, skin conditions) skin sensitization Category 1B (UN-GHS).

11.7. STOT RE

Data for mixture

Not available

Substances

Not available

11.8. STOT SE

Data for mixture

Not available

Substances

butyl methacrylate (CAS: 97-88-1)

Title	:	Not available
Species	:	Not available
Sex	:	Not available

Route of administration	:	Not available
Specific effects	:	Not available
Guideline	:	Not available
Exposure duration/value	:	Not available
Conclusion	:	respiratory tract, (irritation). Specific target organ toxicity - single exposure Category 3 (UN-GHS)
Executive summary	:	Not available

methyl methacrylate (CAS: 80-62-6)

Title	:	Not available
Species	:	Not available
Sex	:	Not available
Route of administration	:	Not available
Specific effects	:	Not available
Guideline	:	Not available
Exposure duration/value	:	Not available
Conclusion	:	Respiratory tract, (Irritation). Specific target organ toxicity - single exposure Category 3 (UN-GHS)
Executive summary	:	Not available

11.9. STOT RE

Data for mixture

Not available

Substances

dibenzoyl peroxide (CAS: 94-36-0)

Species	:	Rat
Sex	:	Not available
Route of administration	:	Ingestion
Target organ of toxicity	:	Not available
Exposure duration	:	29
Exposure duration/unit	:	days
Frequency of treatment	:	Not available
Frequency of treatment/unit	:	Not available
Concentration	:	Not available

Subendpoint	Conclusion
NOAEL: 1.000 mg/kg.	Method: OECD Test Guideline 422. Symptoms: No side effects.

butyl methacrylate (CAS: 97-88-1)

Species	:	Rat
Sex	:	Not available
Route of administration	:	Not available
Target organ of toxicity	:	Not available
Exposure duration	:	Not available
Exposure duration/unit	:	Not available
Frequency of treatment	:	Not available
Frequency of treatment/unit	:	Not available
Concentration	:	Not available

Subendpoint	Conclusion
rat, inhaled, 4 wk, OECD 412. NOAEL: 1.83 mg/l	Result: lesion of the nasal mucosa.
rat, oral, 90 day, OECD 408. NOAEL: 120 mg/kg	-

methyl methacrylate (CAS: 80-62-6)

Species	:	Rat

Sex : Not available
Route of administration : Not available
Target organ of toxicity : Not available
Exposure duration : Not available
Exposure duration/unit : Not available
Frequency of treatment : Not available
Frequency of treatment/unit : Not available
Concentration : Not available

Subendpoint	Conclusion
Rat, in drinking water, 2a, 6 - 2000 ppm. NOAEL: 2000 ppm	Result: no toxic effect.
Rat, inhaled, 2a, 25 - 400 ppm. NOAEL: 25 ppm	Result: Deterioration of the nasal mucosa at 400 ppm.

11.10. Carcinogenicity

Data for mixture

Not available

Substances

dibenzoyl peroxide (CAS: 94-36-0)

Test type : Not available
Species : Not available
Sex : Not available
Guideline : Not available
Route of administration : Not available
Exposure duration/value : Not available
Exposure duration/unit : Not available

Subendpoint	Results/Sex	Operator	Value	Unit
-	-	-	-	-

Conclusion : Animal testing has shown no carcinogenic effects.

butyl methacrylate (CAS: 97-88-1)

Test type : Not available
Species : Not available
Sex : Not available
Guideline : Not available
Route of administration : Not available
Exposure duration/value : Not available
Exposure duration/unit : Not available

Subendpoint	Results/Sex	Operator	Value	Unit
-	-	-	-	-

Conclusion : No specific test data available No indications of critical properties (Effect-structure considerations) (Analogy)

methyl methacrylate (CAS: 80-62-6)

Test type : Not available
Species : Not available
Sex : Not available
Guideline : Not available
Route of administration : Not available
Exposure duration/value : Not available
Exposure duration/unit : Not available

Subendpoint	Results/Sex	Operator	Value	Unit
-	-	-	-	-

Conclusion : Has been shown to be non-carcinogenic in inhalation and ingestion experiments with rats, mice and dogs.

11.11. Reproductive and Developmental Toxicity

Data for mixture

Not available

Substances

dibenzoyl peroxide (CAS: 94-36-0)

Test type : Not available
Species : Not available
Sex : Not available
Guideline : Not available
Route of administration : Not available
Exposure duration/value : Not available
Exposure duration/unit : Not available
Concentration : Not available

Subendpoint	Results/Sex	Operator	Value	Unit
-	-	-	-	-

Conclusion : Note: Not toxic for reproduction.

butyl methacrylate (CAS: 97-88-1)

Test type : Not available
Species : Not available
Sex : Not available
Guideline : Not available
Route of administration : Not available
Exposure duration/value : Not available
Exposure duration/unit : Not available
Concentration : Not available

Subendpoint	Results/Sex	Operator	Value	Unit
-	-	-	-	-

Conclusion : non teratogenic, non embryotoxic. In animal tests, fetotoxic effects have been observed with high dosages. No indication of a harmful effect on the embryo in animal tests. Human health hazard assessment: CMR: No.

Gentamicin, sulfate (salt) (CAS: 1405-41-0)

Test type : Not available
Species : Not available
Sex : Not available
Guideline : Not available
Route of administration : Not available
Exposure duration/value : Not available
Exposure duration/unit : Not available
Concentration : Not available

Subendpoint	Results/Sex	Operator	Value	Unit
-	-	-	-	-

Conclusion : Presumed teratogenic product (reproductive toxicity). CMR effects: Repr.2

methyl methacrylate (CAS: 80-62-6)

Test type	:	Not available
Species	:	Not available
Sex	:	Not available
Guideline	:	Not available
Route of administration	:	Not available
Exposure duration/value	:	Not available
Exposure duration/unit	:	Not available
Concentration	:	Not available

Subendpoint	Results/Sex	Operator	Value	Unit
-	-	-	-	-

Conclusion : Based on animal experiments, no toxic effects on reproduction. non teratogenic, non embryotoxic. No indication of a harmful effect on the embryo in animal tests. Human health risk assessment: CMR: no.

11.12. Genotoxicity

Data for mixture

Test type	:	Human lymphocytes from heparinized whole peripheral blood cultures with a modal chromosome number of 46 ± 2 were be used. The heparinized whole blood was provided by the French Blood Bank of Lyon, France and was non-reactive for the presence of antibody to HIV and hepatisis B surface antigens. The heparinized whole blood was used within 24 hours after blood taking.
Species	:	Not available
Sex	:	Not available
Guideline	:	The study was conducted according to the ISO 10993 Standard: Biological evaluation of medical devices. Part 3 (2003): Test for Genotoxicity, Carcinogenicity and Reproductive Toxicity. Part 12 (2007): Test article preparation and reference materials. OECD Guidlines n°473 (1997): In Vitro Mammalian Chromosome Aberration Test.
Type of method	:	Not available
Route of administration	:	Not available
Exposure duration/value	:	Not available
Exposure duration/unit	:	Not available
Concentration	:	Not available

Subendpoint	Results/Sex	Cytoxicity/Toxicity	Operator	Value	Unit
-	-	-	-	-	-

Conclusion : Under the conditions of this assay, the prepared test article extracts were not considered genotoxic to the human lymphocytes in the presence or absence of S9 metabolic activation. The 0.9% NaCl and EtOH test article extracts met the requirements of the test. The negative and positive controls performed as expected.

Substances

dibenzoyl peroxide (CAS: 94-36-0)

Test type	:	Not available
Species	:	SalmonellaTyphimurium
Sex	:	Not available
Guideline	:	OECD Test Guideline 471
Type of method	:	Ames test
Route of administration	:	Not available
Exposure duration/value	:	Not available
Exposure duration/unit	:	Not available
Concentration	:	Not available

Subendpoint	Results/Sex	Cytoxicity/Toxicity	Operator	Value	Unit
-	-	-	-	-	-

Conclusion : Result : negative

Test type : Not available
Species : Not available
Sex : Not available
Guideline : Not available
Type of method : Not available
Route of administration : Not available
Exposure duration/value : Not available
Exposure duration/unit : Not available
Concentration : Not available

Subendpoint	Results/Sex	Cytoxicity/Toxicity	Operator	Value	Unit
-	-	-	-	-	-

Conclusion : In vivo tests have not shown mutagenic effects.

butyl methacrylate (CAS: 97-88-1)

Test type : Not available
Species : Not available
Sex : Not available
Guideline : Not available
Type of method : Not available
Route of administration : Not available
Exposure duration/value : Not available
Exposure duration/unit : Not available
Concentration : Not available

Subendpoint	Results/Sex	Cytoxicity/Toxicity	Operator	Value	Unit
-	-	-	-	-	-

Conclusion : non-mutagenic in vivo and in vitro tests

methyl methacrylate (CAS: 80-62-6)

Test type : Not available
Species : Not available
Sex : Not available
Guideline : Not available
Type of method : Not available
Route of administration : Not available
Exposure duration/value : Not available
Exposure duration/unit : Not available
Concentration : Not available

Subendpoint	Results/Sex	Cytoxicity/Toxicity	Operator	Value	Unit
-	-	-	-	-	-

Conclusion : Both positive and negative results in in vitro mutagenicity or genotoxicity tests. No experimental data available on genotoxicity in vivo. Overall assessment: non-mutagenic according to internationally recognized criteria.

11.13. In vitro genotoxicity

Data for mixture

Not available

Substances
Not available

11.14. Respiratory sensitisation

Data for mixture
Not available

Substances
Not available

Additional information
Not available

SECTION 12: Ecological information

12.1. Toxicity

Based on available data, the classification criteria are not met.

Acute aquatic toxicity

Substances

dibenzoyl peroxide (CAS: 94-36-0)

Animals/category	:	Fish
Species	:	Oncorhynchus mykiss (rainbow trout)
Test duration	:	96
Unit	:	h
Guideline	:	OECD Test Guideline 203

Subendpoint	Value	Unit
LC50:	0.06	mg/L

Remarks : Not available

Animals/category	:	Daphnia and other aquatic invertebrates
Species	:	Daphnia
Test duration	:	48
Unit	:	h
Guideline	:	OECD Test Guideline 202

Subendpoint	Value	Unit
EC50	0,11	mg/L

Remarks : Not available

Animals/category	:	algea or cyanobacteria
Species	:	Pseudokirchneriella subcapitata (green algae)
Test duration	:	72
Unit	:	h
Guideline	:	OECD Test Guideline 201

Subendpoint	Value	Unit
EC50	0,07	mg/L

Remarks : Not available

Animals/category	:	Not available
Species	:	Not available
Test duration	:	Not available
Unit	:	Not available
Guideline	:	Not available

Subendpoint	Value	Unit
M factor	10	-

Remarks : Not available

Animals/category : bacteria
Species : Not available
Test duration : 30
Unit : min
Guideline : OECD Test Guideline 209. Test method: Inhibition of activated sludge respiration.

Subendpoint	Value	Unit
EC50	35	mg/L

Remarks : Not available

butyl methacrylate (CAS: 97-88-1)

Animals/category : Fish
Species : Oryzias latipes
Test duration : 96
Unit : h
Guideline : OECD 203, semi-static

Subendpoint	Value	Unit
LC50:	5,57	mg/L

Remarks : Not available

Animals/category : Aquatic Invertebrates
Species : Daphnia magna
Test duration : 48
Unit : h
Guideline : OECD 202 part 1, static test

Subendpoint	Value	Unit
EC50	25,4	mg/L

Remarks : Not available

Animals/category : algea or cyanobacteria
Species : Selenastrum capricornutum.
Test duration : 72
Unit : h
Guideline : OECD 201

Subendpoint	Value	Unit
EC50	31,2	mg/L

Remarks : Not available

Animals/category : microorganisms
Species : Pseudomonas putida (Bacillus Pseudomonas putida),
Test duration : Not available
Unit : Not available
Guideline : LTwS-No. 10, 18 h (study carried out by us)

Subendpoint	Value	Unit
EC50	> 253,6	mg/L

Remarks : Not available

methyl methacrylate (CAS: 80-62-6)

Animals/category : Fish
Species : Oncorhynchus mykiss
Test duration : 96
Unit : h
Guideline : OECD 203

Subendpoint	Value	Unit
LC50:	>79	mg/L

Remarks : Not available

Animals/category : Fish
Species : Danio rerio
Test duration : Not available
Unit : Not available
Guideline : OECD 1

Subendpoint	Value	Unit
NOEC:	9,4	mg/L

Remarks : Not available

Animals/category : Aquatic Invertebrates
Species : Daphnia magna
Test duration : 48
Unit : h
Guideline : OECD 202

Subendpoint	Value	Unit
EC50	69	mg/L

Remarks : Not available

Animals/category : algea or cyanobacteria
Species : Selenastrum capricornutum.
Test duration : 72
Unit : h
Guideline : OECD 201

Subendpoint	Value	Unit
EC50	>110	mg/L

Remarks : Not available

Animals/category : algea or cyanobacteria
Species : Selenastrum capricornutum.
Test duration : 72
Unit : h
Guideline : OECD 201

Subendpoint	Value	Unit
NOEC:	>110	mg/L

Remarks : Not available

Animals/category : microorganisms
Species : Pseudomonas putida.
Test duration : 16
Unit : h
Guideline : inhibition test, cell multiplication, Bringmann-Kuhn,

Subendpoint	Value	Unit
EC3	100	mg/L

Remarks : Not available

Chronic aquatic toxicity

Substances

butyl methacrylate (CAS: 97-88-1)

Animals/category : Aquatic Invertebrates
Species : Daphnia magna
Guideline : OECD 202 part 2, circulation
Exposure duration/value : 21
Exposure duration/unit : days

Subendpoint	Value	Unit
NOEC:	1,1	mg/L

Remarks : Not available

Animals/category : Algae/aquatic plants
Species : Pseudokirchneriella subcapitata.
Guideline : OECD 201
Exposure duration/value : 72
Exposure duration/unit : h

Subendpoint	Value	Unit
NOEC:	24,8	mg/L

Remarks : Not available

methyl methacrylate (CAS: 80-62-6)

Animals/category : Aquatic Invertebrates
Species : Daphnia magna
Guideline : OECD 202 part 2, circulation
Exposure duration/value : 21
Exposure duration/unit : days

Subendpoint	Value	Unit
NOEC:	37	mg/L

Remarks : Not available

12.2. Persistence and degradability

The product has not been tested.

Biodegradation

Substances

dibenzoyl peroxide (CAS: 94-36-0)

Inoculum : Not available
Guideline : OECD 301D Test Guideline
Test duration : 28
Unit : days

Parameter	Degradation rate	Unit
Biodegradation	68	%

Remarks : Result: Biodegradable. Note: The 10 day window criterion is not met.

butyl methacrylate (CAS: 97-88-1)

Inoculum : Not available
Guideline : OECD 301 C
Test duration : 28
Unit : days

Parameter	Degradation rate	Unit
-	88	%

Remarks : Easily biodegradable, according to the appropriate OECD test. In air, the material is rapidly degraded by photochemical means. readily biodegradable.

methyl methacrylate (CAS: 80-62-6)

Inoculum : Not available
Guideline : OECD 301 C
Test duration : 14
Unit : days

Parameter	Degradation rate	Unit
-	94	%

Remarks : Easily biodegradable, according to the appropriate OECD test. In the air, matter is rapidly degraded by photochemical means. Biodegradability: easily biodegradable.

12.3. Bioaccumulative potential

The product has not been tested.

Bioconcentration factor (BCF)

Substances

butyl methacrylate (CAS: 97-88-1)

Species : Not available
Guideline : Not available
Log kow : Not available

Bioconcentration factor (BCF)
-

Remarks : The substance is absorbed by the metabolic system, so do not expect a significant amount of enrichment in the body.

methyl methacrylate (CAS: 80-62-6)

Species : Not available
Guideline : Not available
Log kow : Not available

Bioconcentration factor (BCF)
-

Remarks : Given the distribution coefficient in n-octanol-water (log Pow), enrichment in organisms is not to be expected.

12.4. Mobility in soil

The product has not been tested.

Mobility

Substances

dibenzoyl peroxide (CAS: 94-36-0)

Distribution : Not available
Transport type : Not available
Guideline : Not available
Superficial tension : Not available

Parameter	Value
Log KOC	3,8

Remarks : Adsorption/Soil. Middle: Soil.

butyl methacrylate (CAS: 97-88-1)

Distribution : Not available
Transport type : Not available
Guideline : Not available
Superficial tension : Not available

Parameter	Value
-	-

Remarks : Given the adsorption behavior, the material can bind to the firm soil phase, sediment or decantation mud. From the surface of the water, matter slowly evaporates into the atmosphere. If the substance reaches the environment, it preferably remains in the compartment from which it left.

methyl methacrylate (CAS: 80-62-6)

Distribution : Not available
Transport type : Not available
Guideline : Not available
Superficial tension : Not available

Parameter	Value
-	-

Remarks : We should not expect a bond on the firm soil phase, sediment or decantation mud. From the surface of the water, matter slowly evaporates into the atmosphere. If the substance reaches the environment, it preferably remains in the compartment from which it left.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

12.7. Additional ecotoxicological information

Not available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.
Waste requiring special supervision.
Dispose of waste according to applicable legislation.
Delivery to an approved waste disposal company.
Non-contaminated packages must be recycled or disposed of.
Contaminated packing must be completely emptied and can be reused after proper cleaning.
Packing which cannot be properly cleaned must be disposed of.
Handle contaminated packages in the same way as the substance itself.
Dispose of waste according to applicable legislation.
For recycling, contact manufacturer.
Collect the waste separately.
Consult the appropriate authorities about waste disposal.
Do not mix with other wastes.
The waste is to be kept separate from other types of waste until its disposal.
Concerning the waste it has to be checked, whether a transport authorisation is required.

13.2. Additional information

Not available

SECTION 14: Transport information

14.1. UN number

Not available

14.2. UN proper shipping name

Not available

14.3. Transport hazard class(es)

Not available

14.4. Packing group

Not available

14.5. Environmental hazards

Not available

14.6. Special precautions for user

Not available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not available

14.8. Additional information

Not available

SECTION 15: Regulatory information

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

This SDS has been established in accordance with REACH regulation, including its amendments: REACH Regulation (EC) No 1907/2006. This SDS has been established in accordance with CLP regulation, including its amendments: CLP Regulation EC No. 1272/2008.

Not available

15.2. Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier. For this substance/mixture a chemical safety assessment has been elaborated. For this mixture, the relevant data of the Substances' Chemical safety assessment are integrated in the sections of the SDS.

15.3. Additional information

Not available

SECTION 16: Other information

Creation date:	18/02/2020
Version date:	18/02/2020
Printing date:	25/02/2020

16.1. Indication of changes

Not applicable (first edition of the MSDS).

16.2. Abbreviations and acronyms

ADN/ADNR: Regulations concerning the transport of dangerous substances in barges on the waterways. ADR/RID: European Agreement concerning the International Carriage of Dangerous Goods by Road/Regulations concerning the international carriage of dangerous goods by rail. CAS: Chemical Abstract Service Number. IATA: International Air Transport Association. IMDG: International Maritime Dangerous Goods Code. DPD Dangerous Preparation Directive. UN number: United Nations number. No EC: European Commission Number. CLP: Classification, labeling and packaging. VPvB: very persistent and very bioaccumulative substances.

16.3. Key literature references and sources for data

No data available.

16.4. Classification for mixtures and used evaluation method according to regulation (EC) 1272/2008 [CLP]

Classification of the mixture is in accordance with the evaluation method described in Regulation (EC) No 1272/2008.

16.5. Relevant R-, H- and EUH-phrases (Number and full text)

H225	Flam. Liq. 2	Highly flammable liquid and vapour.
H226	Flam. Liq. 3	Flammable liquid and vapour.
H241	Org. Perox. B	Heating may cause a fire or explosion.
H315	Skin Irrit. 2	Causes skin irritation.
H317	Skin Sens. 1	May cause an allergic skin reaction.
H319	Eye Irrit. 2	Causes serious eye irritation
H334	Resp. Sens. 1	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	STOT SE 3 H335	May cause respiratory irritation

16.6. Training advice

Not available

16.7. Additional information

Not available

The information given in this Safety Data Sheet is based on our present knowledge and on european and national regulations.This Safety Data Sheet describes safety requirements relative to identified uses, it doesn't guarantee all the product properties particularly in the case of non identified uses.The product mustn't be used for any uses other than those identified under heading 1.Since the user's working conditions are not known by us, it is the responsability of the user to take all necessary measures to comply with legal requirements for specific uses and avoid negative health effects.