

1 Identification of the substance/preparation and of the company/undertaking

· **Product details**

· **Trade name:** WET BOPTA

· **Chemical name:**

4-carboxy-5,8,11-tris-(carboxymethyl)-1-phenyl-2-oxa-5,8,11-triaza-tridecan-13-oic acid, wet with acetone and water

· **Application of the substance / the preparation** Pharmaceutical preparation

· **Manufacturer/Supplier:**

Bracco Imaging S.p.A.

Via E. Folli, 50

20134 Milano

tel. +39 (0)2 21771

· **Further information obtainable from:** hse@bracco.com

· **Information in case of emergency:**

Emergency contact:

Ospedale Niguarda Ca' Granda - Milano

Antivenoms Centre: +39 (0)2 66101029

In case of need, call any emergency telephone number available.

2 Hazards identification

· **Hazard description:**



N Dangerous for the environment

· **Information concerning particular hazards for human and environment:**

See also Sections 11 and 12.

R 10 Flammable.

R 50 Very toxic to aquatic organisms.

· **Classification system:**

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

· **GHS label elements**



Danger

H228 - Flammable solid.



Warning

H400 - Very toxic to aquatic life.

· **Prevention:**

P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

P241 Use explosion-proof electrical/ventilating/lighting/equipment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P240 Ground/bond container and receiving equipment.

P273 Avoid release to the environment.

· **Disposal:**

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

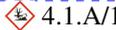
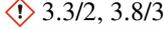
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3 Composition/information on ingredients

- **Chemical characterization**
- **Description:** Mixture: consisting of the following components.

· **Dangerous components:**

CAS: 113786-33-7	Boptaclien	 N; R 50 Warning: 	60.0%
CAS: 67-64-1 EINECS: 200-662-2	acetone	 Xi,  F; R 11-36-66-67 Danger:  Warning: 	9.0%

- **Additional information:** For the wording of the listed risk phrases refer to section 16.

4 First aid measures

- **General information:** See also Sections 2 and 11.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**
Wash with water and rinse thoroughly.
Remove contaminated clothing.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult a doctor.

5 Fire-fighting measures

- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards caused by the substance, its products of combustion or resulting gases:**
During heating or in case of fire poisonous gases are produced.
- **Protective equipment:**
Firefighters should wear adequate personal protective equipment with protection of respiratory tract (self-contained breathing apparatus).
See also Section 8.
- **Additional information**
Cool endangered receptacles with water spray.
Collect contaminated fire fighting water separately. It must not enter the sewage system.

6 Accidental release measures

- **Person-related safety precautions:**
Wear protective equipment. Keep unprotected persons away.
See also Section 8.
Use respiratory protective device against the effects of fumes/dust/aerosol.
Ensure adequate ventilation (see also Section 3).
- **Measures for environmental protection:**
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
- **Measures for cleaning/collecting:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

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Pick up mechanically.
Send for recovery or disposal in suitable receptacles.
Do not flush with water or aqueous cleansing agents

Additional information:

Use according to good working practice and avoid releasing product into the environment (see also Section 12).

7 Handling and storage

Handling:

Information for safe handling:

Use only in well ventilated areas.

Operations must be carried on in closed systems or, alternatively, in facilities fitted with exhaust hoods or equivalent vapours and dusts capturing devices.

Take note of emission threshold.

Information about fire - and explosion protection:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

Use explosion protected electrical equipment, if required.

Storage:

Requirements to be met by storerooms and receptacles: Store in a cool location.

Information about storage in one common storage facility: Store away from oxidizing agents.

Further information about storage conditions:

Store in dry conditions.

Store receptacle in a well ventilated area.

Keep container tightly sealed.

Protect from heat and direct sunlight.

8 Exposure controls/personal protection

Additional information about design of technical facilities: No further data; see Section 7.

Ingredients with limit values that require monitoring at the workplace:

67-64-1 acetone

WEL Short-term value: 3620 mg/m³, 1500 ppm

Long-term value: 1210 mg/m³, 500 ppm

Additional information: Valid data and limit values in date of revision were used as basis.

Personal protective equipment:

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs, beverages and feed.

Clean skin thoroughly immediately after handling the product.

Respiratory protection:

Short term filter device:

organic vapour filter (type A)

Self-contained breathing apparatus for emergency use (for instance, large fires).

Protection of hands:



Protective gloves

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- **Material of gloves**
PVC or PE gloves
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:**



Tightly sealed goggles

- **Body protection:** Normal working clothes.
- **Limitation and supervision of exposure into the environment** See also Section 7.1

9 Physical and chemical properties

· General Information

Form:	Solid Powder Solid mass
Colour:	White
Odour:	Characteristic

· Change in condition

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

· **Flash point:** > 21°C

· **Ignition temperature:** 450°C

· **Self-igniting:** Product is not selfigniting.

· **Danger of explosion:** Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

· **Density:** Not determined.

· Solubility in / Miscibility with

water: Not miscible or difficult to mix.

· Solvent content:

Organic solvents: 9.0 %

· **Solids content:** 60.0 %

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:**
No decomposition if used and stored according to specifications.
- **Materials to be avoided:** Oxidants.
- **Dangerous decomposition products:**
Carbon monoxide and carbon dioxide

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11 Toxicological information

· Acute toxicity:**· LD/LC50 values relevant for classification:****113786-33-7 Boptaclien**

LD0 > 2000 mg/kg (rat)

· Primary irritant effect:**· on the skin:** No irritating effect.**· on the eye:** No irritating effect.**· Sensitization:** No sensitizing effects known.**· Sensitisation** No evidence reported in working practice.

12 Ecological information

· Ecotoxicological effects:**· Aquatic toxicity:****113786-33-7 Boptaclien**

EC50 150 mg/l (daphnia)

LC50 380 mg/l (fish)

trota arcobaleno

· Remark: Very toxic for fish**· General notes:**

Avoid transfer into the environment.

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

Also poisonous for fish and plankton in water bodies.

Very toxic for aquatic organisms

13 Disposal considerations

· Product:**· Recommendation**

Product's surplus or waste resulting from use must be handled according to precautions and individual protective measures as indicated under Sections 7 and 8.

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

· Uncleaned packaging:**· Recommendation:** Disposal must be made according to official regulations.

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14 Transport information

· **Land transport ADR/RID (cross-border)**



- **ADR/RID class:** 3 Flammable liquids.
- **Danger code (Kemler):** 33
- **UN-Number:** 1993
- **Packaging group:** II
- **Hazard label:** 3
- **Special marking:** Symbol (fish and tree)
- **Description of goods:** 1993 FLAMMABLE LIQUID, N.O.S. (ACETONE)

· **Maritime transport IMDG:**



- **IMDG Class:** 3
- **UN Number:** 1993
- **Label:** 3
- **Packaging group:** II
- **EMS Number:** F-E,S-E
- **Marine pollutant:** Yes
- **Proper shipping name:** FLAMMABLE LIQUID, N.O.S. (ACETONE)

· **Air transport ICAO-TI and IATA-DGR:**



- **ICAO/IATA Class:** 3
- **UN/ID Number:** 1993
- **Label:** 3
- **Packaging group:** II
- **Proper shipping name:** FLAMMABLE LIQUID, N.O.S. (ACETONE)

- **UN "Model Regulation":** UN1993, FLAMMABLE LIQUID, N.O.S., 3, II
- **Environmental hazards:** Product contains environmentally hazardous substances: Boptaclien

15 Regulatory information

· **Labelling according to EU guidelines:**

The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials.

· **Code letter and hazard designation of product:**

N Dangerous for the environment

· **Risk phrases:**

- 10 Flammable.
- 50 Very toxic to aquatic organisms.

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· **Safety phrases:**

- 9 Keep container in a well-ventilated place.
- 16 Keep away from sources of ignition - No smoking.
- 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- 57 Use appropriate container to avoid environmental contamination.

· **National regulations:**

The product is subject to be labeled according with the prevailing version of the regulations on hazardous substances.
D.lgs. n°152/2006 and subsequent amendments.

16 Other information

This information is based on our present knowledge; it is believed to be accurate and represent the best available set of data at the date of revision. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

This sheet voids and takes over any other MSDS' previous release concerning this product.

· **Relevant R-phrases**

- 11 Highly flammable.
- 36 Irritating to eyes.
- 50 Very toxic to aquatic organisms.
- 66 Repeated exposure may cause skin dryness or cracking.
- 67 Vapours may cause drowsiness and dizziness.

· **Training hints**

All persons handling this product should be informed on the existence of the hazard, on any possible risk they might be subjected to and about all required protective measures to prevent such a damage or to reduce the exposition.

· **Department issuing MSDS:** HSE Department - Bracco Group

· **Contact:** Ing. Daniela Arnoldi

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organization
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent

· **Sources**

- Stazione Sperimentale per i Combustibili (S. Donato -MI-): Report n° B25149 8th September 1992
- Stazione Sperimentale per i Combustibili (S. Donato -MI-): Relazione n° B112290 del 26th July 1989
- Battelle Europa Geneva Research Centres; final reports of studies on:
 1. The acute oral toxicity of 34 chemical substances in the rat (limit test at 2000 mg/kg)
- TOX BR-91-01-BG
 2. The acute dermal toxicity of 34 chemical substances in the rat (limit test at 2000 mg/kg)
- TOX 1-91
 3. The mutagenic potential of 34 chemical substances MUTA 1-91
Synthetica SA - Centre de Recherche de Geneve (1991-1992)
 4. The acute toxicity (skin irritation) of chemical substances in the rabbit
- TOX 2-92
 5. The acute toxicity (eye irritation) of chemical substances in the rabbit
- TOX 3-92
- 6. Internal data

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- * **Data compared to the previous version altered.**
- data updating on the basis of the latest amendments.
- adaptation of the form according to Regulation 1907/2006/CE.

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