

Safety Data Sheet

1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Code: **1782D, 1782Q**
Product name: **Bio-Clear**

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

Intended use: **In vitro medical-diagnostic disposable. Reagent for microscopy.**

1.3. Details of the supplier of the safety data sheet

Name: **Bio-Optica Milano S.p.a.**
Full address: **via San Faustino, 58**
District and Country: **20134 Milano Italia**
Tel.: **0039 02 2127131**
Fax: **0039 02 2153000**

e-mail address of the competent person responsible for the Safety Data Sheet: **info@bio-stain.it**

Product distribution by: **Bio-Optica Milano S.p.a.**

1.4. Emergency telephone number

For urgent inquiries refer to: **Please contact the nearest Tossicology and Antivenin Center**

2. Hazards identification.

2.1. Classification of the substance or mixture.

The product is classified as hazardous pursuant to the provisions set forth in Directives 67/548/EEC and 1999/45/EC and/or EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of EC Regulation 1907/2006 and subsequent amendments.

Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

2.1.1. Regulation 1272/2008 (CLP) and following amendments and adjustments.

Hazard classification and indication:

Flam. Liq. 3	H226
Asp. Tox. 1	H304
Skin Irrit. 2	H315
Skin Sens. 1	H317
Aquatic Chronic 1	H410

2.1.2. Directive 67/548/EEC and following amendments and adjustments.

Danger Symbols: **Xn-N**

R phrases: **10-38-43-50/53-65**

The full wording of the Risk (R) and hazard (H) phrases is given in section 16 of the sheet.

2.2. Label elements.

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Pictograms:



Warning: Danger

Hazard indication:

H226 Flammable liquid and vapour.
H304 May be fatal if swallowed and enters airways.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H410 Very toxic to aquatic life with long lasting effects.

Caution recommendations:

P210 Keep away from heat / sparks / open flames / hot surfaces. No smoking.
P264 Wash hands thoroughly after handling.
P280 Wear protective gloves / protective clothing / eye protection / face protection.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor / physician.
P303+P361+P353 IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower.

Contains: (R)-P-MENTHA-1,8-DIENE
Alfa Pinene

2.3. Other hazards.

Information not available.

3. Composition/information on ingredients.

3.1. Substances.

Contains:

Identification.	Conc. %.	Classification 67/548/EEC.	Classification 1272/2008 (CLP).
(R)-P-MENTHA-1,8-DIENE			
CAS. 5989-27-5	50 - 100	R10, Xi R38, Xi R43, N R50/53, Note C	Flam. Liq. 3 H226, Skin Irrit. 2 H315, Skin Sens. 1 H317, Aquatic Acute 1 H400, Aquatic Chronic 1 H410, Note C
EC. 227-813-5			
INDEX. 601-029-00-7			
7-Methyl-3-methylene-1,6-octadiene			
CAS. 123-35-3	1 - 5	R10, Xi R36/37/38	Flam. Liq. 3 H226, Eye Irrit. 2 H319, Skin Irrit. 2 H315, STOT SE 3 H335
EC. 204-622-5			
INDEX. -			
Alfa Pinene			
CAS. 7785-26-4	1 - 2,5	Xn R65, Xi R43, N R50/53	Flam. Liq. 3 H226, Asp. Tox. 1 H304, Eye Irrit. 2 H319, Skin Irrit. 2 H315, Skin Sens. 1 H317, Aquatic Chronic 1 H410
EC. 232-077-3			
INDEX. -			

T+ = Very Toxic(T+), T = Toxic(T), Xn = Harmful(Xn), C = Corrosive(C), Xi = Irritant(Xi), O = Oxidizing(O), E = Explosive(E), F+ = Extremely Flammable(F+), F = Highly Flammable(F), N = Dangerous for the Environment(N)

The full wording of the Risk (R) and hazard (H) phrases is given in section 16 of the sheet.

3.2. Mixtures.

Information not relevant.

4. First aid measures.

4.1. Description of first aid measures.

EYES: Irrigate copiously with clean, fresh water for at least 15 minutes.

Seek medical advice.

SKIN: Immediately wash with plenty of water. Remove all contaminated clothing. Obtain immediate medical attention. Wash contaminated clothing separately before using them again.

INHALATION: Remove to open air. If breathing is irregular or stopped, administer artificial respiration. Obtain immediate medical attention.

INGESTION: Obtain immediate medical attention. Induce vomiting only if indicated by the doctor. Give nothing by mouth to an unconscious person.

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

For symptoms and effects caused by the contained substances see chap. 11.

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

Follow doctor's orders.

5. Firefighting measures.

5.1. Extinguishing media.

SUITABLE EXTINGUISHING MEDIA

The extinction equipment should contain carbon dioxide, foam or chemical powders. For product leaks and spills that have not caught fire, nebulised water can be used to dispel flammable fumes and protect the individuals taking part in stemming the leak.

EXTINGUISHING MEDIA WHICH SHALL NOT BE USED FOR SAFETY REASONS

Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

5.2. Special hazards arising from the substance or mixture.

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Excess pressure may form in containers exposed to fire at a risk of explosion.

Do not breathe combustion products (carbon oxide, toxic pyrolysis products, etc).

5.3. Advice for firefighters.

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Hardhat with visor, fireproof clothing (fireproof jacket and trousers with ties around arms, legs and waist) work gloves (fireproof, cut proof and dielectric), self-respirator (self-protector).

6. Accidental release measures.

6.1. Personal precautions, protective equipment and emergency procedures.

Eliminate all sources of ignition (cigarettes, flames, sparks, etc.) from the leakage site. If there are no contraindications, spray solid products with water to prevent the formation of dust. Use breathing equipment if fumes or powders are released into the air. Block the leakage if there is no hazard. Do not handle damaged containers or the leaked product before donning appropriate protective gear. For information on risks for the environmental and health, respiratory tract protection, ventilation and personal protection equipment, see the other sections of this sheet.

6.2. Environmental precautions.

The product must not penetrate the sewers, surface water, ground water and neighbouring areas.

6.3. Methods and material for containment and cleaning up.

Use inert absorbent material (sand, vermiculite, diatomaceous earth, Kieselguhr, etc.) to soak up leaked product. Collect the majority of the remaining material and deposit it in containers for disposal. If there are no contraindications, use jets of water to eliminate product residues.

Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections.

Any information on personal protection and disposal is given in sections 8 and 13.

7. Handling and storage.

7.1. Precautions for safe handling.

Avoid bunching of electrostatic charges.

Do not smoke. Do not spray on flames or sparks. Vapours may catch fire and an explosion may occur; vapours accumulation is therefore to be avoided by leaving windows and doors open and ensuring a good ventilation (draught). Without adequate ventilation, vapours may accumulate on the floor (low layers) and catch fire even at a distance, if ignited, with the danger of backfire.

7.2. Conditions for safe storage, including any incompatibilities.

Store in a place where adequate ventilation is ensured, away from direct sunlight at a temperature below 50 °C, far from any combustion sources.

7.3. Specific end use(s).

Information not available.

Bio-Clear

8. Exposure controls/personal protection.

8.1. Control parameters.

Information not available.

8.2. Exposure controls.

As the use of adequate technical equipment must always take priority over personal protection equipment, make sure that the workplace is well aired through effective local aspiration or bad air vent. If such operations do not make it possible to keep the concentration of the product below the permitted workplace exposure thresholds a suitable respiratory tract protection must be used. See product label for hazard details during use. Ask your chemical substance suppliers for advice when choosing personal protection equipment. Personal protection equipment must comply with the rules in force indicated below.

HAND PROTECTION

Protect hands with category II (ref. Directive 89/686/EEC and standard EN 374) work gloves, such as those in PVC, neoprene, nitril or equivalent. The following should be considered when choosing work glove material: degradation, breakage times and permeation. Work glove resistance to preparations should be checked before use, as it can be unpredictable. Gloves' limit depends on the duration of exposure.

EYE PROTECTION

Wear protective airtight goggles (ref. standard EN 166).

SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (ref. Directive 89/686/CEE and standard EN 344). Wash body with soap and water after removing overalls.

RESPIRATORY PROTECTION

If the threshold value for one or more of the substances present in the preparation for daily exposure in the workplace or to a fraction established by the company's prevention and protection service is exceeded, wear a mask with an A or universal filter, the class (1, 2 or 3) of which must be chosen according to the limit concentration of use (ref. standard EN 141).

The use of breathing protection equipment, such as masks with organic vapour and dust/mist cartridges, is necessary in the absence of technical measures limiting worker exposure. The protection provided by masks is in any case limited.

If the substance in question is odourless or its olfactory threshold is higher than the relative exposure limit and in the event of an emergency, or when exposure levels are unknown or the concentration of oxygen in the workplace is less than 17% volume, wear self-contained, open-circuit compressed air breathing apparatus (ref. standard EN 137) or fresh air hose breathing apparatus for use with full face mask, half mask or mouthpiece (ref. standard EN 138).

An emergency eye washing and shower system must be provided.

In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.

9. Physical and chemical properties.

9.1. Information on basic physical and chemical properties.

Appearance	liquid
Colour	colourless
Odour	characteristic
Odour threshold.	Not available.
pH.	/
Melting or freezing point.	Not available.
Boiling point.	Not available.
Distillation range.	Not available.
Flash point.	45 °C.
Evaporation Rate	Not available.
Flammability of solids and gases	Not available.
Lower inflammability limit.	Not available.
Upper inflammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	Not available.
Specific gravity.	Not available.
Solubility	insoluble in water
Partition coefficient: n-octanol/water	Not available.
Ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not available.
Reactive Properties	Not available.

9.2. Other information.

VOC (Directive 1999/13/EC) :	95,00 %
VOC (volatile carbon) :	83,68 %

10. Stability and reactivity.

10.1. Reactivity.

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability.

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions.

The vapours may also form explosive mixtures with the air.

10.4. Conditions to avoid.

Avoid overheating, electrostatic discharge and all sources of ignition.

10.5. Incompatible materials.

Information not available.

10.6. Hazardous decomposition products.

In the event of thermal decomposition or fire, vapours potentially dangerous to health may be released.

11. Toxicological information.

11.1. Information on toxicological effects.

Acute effects: contact with skin may cause: irritation, erythema, edema, dryness and chapped skin. Vapour inhalation may slightly irritate the upper respiratory tract. Ingestion may cause health disorders, including stomach pain and sting, nausea and sickness.

Upon contact with skin, this product causes sensitization (dermatitis). Dermatitis derives from skin irritation on the areas which repeatedly come into contact with the sensitizing agent. Cutaneous lesions may include: erythemas, edemas, papules, vesicles, pustules, scurries, ulcerations and exudative phenomena, whose intensity varies according to illness seriousness and affected areas. Erythemas, edemas and exudative phenomena prevail during the acute phase. Scuffy skin, dryness, ulcerations and skin thickening prevail during the chronic phase.

The introduction of even small quantities of this liquid into the respiratory system in case of ingestion or vomit may cause bronchopneumonia and pulmonary edema.

7-Methyl-3-methylene-1,6-octadiene

LD50 (Oral): > 5000 mg/kg

LD50 (Dermal): > 5000 mg/kg

12. Ecological information.

This product is dangerous for the environment and highly toxic for aquatic organisms. In the long term, it may even have negative effects on aquatic environment.

12.1. Toxicity.

(R)-P-MENTHA-1,8-DIENE

LC50 (96h): 35 mg/l/96h *Oncorhynchus mykiss*

EC50 (48h): 69,6 mg/l/48h *Daphnia pulex*

12.2. Persistence and degradability.

Information not available.

12.3. Bioaccumulative potential.

Information not available.

12.4. Mobility in soil.

Information not available.

12.5. Results of PBT and vPvB assessment.

Information not available.

12.6. Other adverse effects.

Information not available.

13. Disposal considerations.

13.1. Waste treatment methods.

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

14. Transport information.

These goods must be transported by vehicles authorized to the carriage of dangerous goods according to the provisions set out in the current edition of the Code of International Carriage of Dangerous Goods by Road (ADR) and in all the applicable national regulations. These goods must be packed in their original packagings or in packagings made of materials resistant to their content and not reacting dangerously with it. People loading and unloading dangerous goods must be trained on all the risks deriving from these substances and on all actions that must be taken in case of emergency situations.

Road and rail transport:

ADR/RID Class: 3 UN: 2319
Packing Group: III
Label: 3
Proper Shipping Name: TERPENE HYDROCARBONS, N.O.S. (D-Limonene)



Carriage by sea (shipping):

IMO Class: 3 UN: 2319
Packing Group: III
Label: 3
Marine Pollutant: NO
Proper Shipping Name: TERPENE HYDROCARBONS, N.O.S. (D-Limonene)



Transport by air:

IATA: 3 UN: 2319
Packing Group: III
Label: 3
Proper Shipping Name: TERPENE HYDROCARBONS, N.O.S. (D-Limonene)



15. Regulatory information.

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

Seveso category. 9i, 6

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.

Product.

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Substances in Candidate List (Art. 59 REACH).

None.

Substances subject to authorisation (Annex XIV REACH).

None.

Healthcare controls.

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

16. Other information.

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Flam. Liq. 3 Flammable liquid, category 3
Skin Irrit. 2 Skin irritation, category 2
Skin Sens. 1 Respiratory / skin sensitization, category 1

Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic toxicity category 1
Eye Irrit. 2	Eye irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
Asp. Tox. 1	Aspiration hazard, category 1
H226	Flammable liquid and vapour.
H304	May be fatal if swallowed and enters airways.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Text of risk (R) phrases mentioned in section 2-3 of the sheet:

R10	FLAMMABLE.
R36/37/38	IRRITATING TO EYES, RESPIRATORY SYSTEM AND SKIN.
R38	IRRITATING TO SKIN.
R43	MAY CAUSE SENSITIZATION BY SKIN CONTACT.
R50/53	VERY TOXIC TO AQUATIC ORGANISMS, MAY CAUSE LONG-TERM ADVERSE EFFECTS IN THE AQUATIC ENVIRONMENT.
R65	HARMFUL: MAY CAUSE LUNG DAMAGE IF SWALLOWED.

GENERAL BIBLIOGRAPHY

1. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and adjustments
3. Regulation (EC) 1907/2006 (REACH) of the European Parliament
4. Regulation (EC) 1272/2008 (CLP) of the European Parliament
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EC) 453/2010 of the European Parliament
7. The Merck Index. - 10th Edition
8. Handling Chemical Safety
9. Niosh - Registry of Toxic Effects of Chemical Substances
10. INRS - Fiche Toxicologique (toxicological sheet)
11. Patty - Industrial Hygiene and Toxicology
12. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product .

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Changes to previous review:

The following sections were modified:

01.