

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING[#]

1.1. Product identifier:

DIPHOTERINE®

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

1.2.1. Relevant identified uses of the substance or mixture:

Eye and skin washing of irritant and corrosive chemical splashes.

1.2.2. Uses advised against:

DIPHOTERINE® solution has limited action on hydrofluoric acid or fluorides in acidic medium splashes. In such events, it is recommended to use HEXAFLUORINE® solution.

1.3. Details of the supplier of the safety data sheet:

PREVOR

Moulin de Verville

BP1

95760 VALMONDOIS

FRANCE

Phone number: +33(0)1 30 34 76 76

Fax: +33(0)1 30 34 76 70

fds@prevor.com

www.prevor.com

1.4. Emergency telephone number:

+33(0)1 30 34 76 76 (office hours, GMT+1).

SECTION 2. HAZARDS IDENTIFICATION[#]

2.1. Classification of the substance or mixture:

Physical hazards: not classified.

Health hazards: not classified.

Environmental hazards: not classified.

2.2. Label elements:

No labelling.

2.3. Other hazards:

None.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS[#]

The 3.1 section is only applied to substances (not applicable for DIPHOTERINE® solution).

3.2. Mixtures:

No hazardous ingredients.

SECTION 4. FIRST AID MEASURES[#]

4.1. Description of first aid measures:

DIPHOTERINE® solution is intended for the first aid washing in case of eye and skin irritant and corrosive chemical splashes. It does not generate hazards and thus does not require any emergency care in case of eye or skin contact. Inhalation and ingestion are not applicable routes of exposure.

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

No known side effects.

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

No medical care required.

SECTION 5. FIREFIGHTING MEASURES#

5.1. Extinguishing media:

This mixture is non-flammable.

5.2. Special hazards arising from the substance or mixture:

No hazard.

5.3. Advice for firefighters:

No specific precautions.

SECTION 6. ACCIDENTAL RELEASE MEASURES#

6.1. Personal precautions, protective equipment and emergency procedures:

In case of ocular contact and for ocular comfort, wash with AFTERWASH II® solution.

6.2. Environmental precautions:

Even if this mixture is not ecotoxic, avoid spills into the environment (sewers, rivers, soils).

6.3. Methods and material for containment and cleaning up:

Set up a retention enclosure or a sewer sealing.

Aspirate or absorb DIPHOTERINE® solution with POLYCAPTOR® universal absorbent for example.

6.4. Reference to other sections:

See section 13.

SECTION 7. HANDLING AND STORAGE#

7.1. Precautions for safe handling:

No special precautions.

7.2. Conditions for safe storage, including any incompatibilities:

Keep the solution in its original closed packaging.

Do not use after expiration date.

If possible, store in a dry place, away from frost or any heating source.

The storage temperature is between 2 °C and 50 °C.

Use temperature is between 15 °C and 35 °C.

Do not store in a corrosive environment without a wall station or protective case.

7.3. Specific end use(s):

Washing of ocular or cutaneous irritant or corrosive chemical splashes.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION#

8.1. Control parameters:

None.

8.2. Exposure controls:

8.2.1. Appropriate engineering controls:

No special precautions.

8.2.2. Individual protection measures, such as personal protective equipment:

Eye/face protection:

No special precautions.

Skin protection:

No special precautions.

Respiratory protection:

No special precautions.

Thermal hazards:

No special precautions.

8.2.3. Environmental exposure controls:

None.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES[#]

9.1. Information on basic physical and chemical properties:

- a) Physical state:
Clear liquid (in storage conditions).
- b) Colour:
Colourless.
- c) Odour:
Odourless.
- d) Melting point / freezing point:
-1 °C.
- e) Boiling point or initial boiling point and boiling range:
100 °C.
- f) Flammability:
The mixture is non-flammable.
- g) Lower and upper explosion limit:
Non applicable because the mixture is non-flammable.
- h) Flash point:
Not applicable because the mixture is non-flammable.
- i) Auto-ignition temperature:
Not applicable because the mixture is non-flammable.
- j) Decomposition temperature:
Possible thermal decomposition at 100°C and above.
- k) pH:
pH from 7.2 to 7.7 (at 20°C).
- l) Kinematic viscosity:
Similar to water at 20 °C and at atmospheric pressure (1 mPa.s).
- m) Solubility:
Miscible with water.
Poorly miscible in organic solvents.
- n) Partition coefficient n-octanol/water (log value):
Miscible with water.
- o) Vapour pressure:
18 mmHg (at 20 °C).
- p) Density and/or relative density:
1.032 (voluminal mass = 1.032 g.cm⁻³).
- q) Relative vapour density:
Not determined.
- r) Particle characteristics:
Not applicable because the mixture is liquid.

9.2. Other information:

- a) Corrosive to metals:
Metal surfaces are subject to corrosion. They must be rinsed with water and wiped with a cloth in case of contact with DIPHOTERINE® solution.

[#] Indicates data modified since last update.

SECTION 10. STABILITY AND REACTIVITY[#]

10.1. Reactivity:

No reaction.

10.2. Chemical stability:

Stable.

10.3. Possibility of hazardous reactions:

None.

10.4. Conditions to avoid:

Do not store at a temperature lower than 2°C or at a temperature higher than 50°C.
For MICRO DAP and MINI DAP sprays, do not puncture or expose to sunlight.

10.5. Incompatible materials:

None known to date.

10.6. Hazardous decomposition products:

None.

SECTION 11. TOXICOLOGICAL INFORMATION[#]

11.1. Information on hazard classes as defined in Regulation (EC) N° 1272/2008:

a) Acute toxicity:

Non-toxic by oral exposure, LD₅₀ (oral in rat) > 2000 mg.kg⁻¹.

b) Skin corrosion / irritation:

Non-irritant and non-corrosive (in vitro tests Dermal Irritation® method).

c) Serious eye damage / irritation:

Non-irritant and non-corrosive (in vitro tests on human fibroblasts).

d) Respiratory or skin sensitisation:

Non-sensitising (Magnusson & Kligman method on guinea pig).

Hypoallergenic (Marzulli-Maibach method on volunteers).

Non anti-inflammatory (MTT in vitro test and IL-1 α pro-irritation potential).

e) Germ cell mutagenicity:

Non-mutagenic (negative Ames test).

f) Carcinogenicity:

Not determined.

g) Reproductive toxicity:

Not determined.

h) STOT – single exposure:

Not determined.

i) STOT – repeated exposure:

Not determined.

j) Aspiration hazard:

Not determined.

11.2. Information on other hazards:

a) Endocrine disrupting properties:

None.

b) Cytotoxicity:

Non-cytotoxic (MTT test on fibroblasts).

c) Local skin tolerance (occlusive test):

Non-irritant.

d) Local skin tolerance on damaged skin / skin healthy (non-occlusive and semi-occlusive test):

No irritant or toxic effect (rabbit test).

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SECTION 12. ECOLOGICAL INFORMATION[#]

DIPHOTERINE® solution is not harmful if released into the environment.

12.1. Toxicity:

12.1.1. Microtoxicity:

No known adverse effects on *Photobacterium phosphoreum*:

EC₅₀ 15 min at 8.63 % (or at 5136 mg.L⁻¹).

EC₅₀ 30 min at 9.8 % (or at 5832 mg.L⁻¹).

12.1.2. Aquatic toxicity:

No known adverse effects on *Daphnia Magna*:

EC₅₀ 24h at 9.5 % (or at 5664 mg.L⁻¹).

12.2. Persistence and degradability:

Not persistent.

12.3. Bioaccumulative potential:

DIPHOTERINE® solution is not bioaccumulative.

12.4. Mobility in soil:

Not determined.

12.5. Results of PBT and vPvB assessment:

Not applicable because the chemical safety report is not required.

12.6. Endocrine disrupting properties:

None.

12.7. Other adverse effects:

No known adverse effects known to date.

SECTION 13. DISPOSAL CONSIDERATIONS[#]

13.1. Waste treatment methods:

No specific disposal measures for this non-hazardous aqueous solution (possible waste code 16 10 02).

DAP autonomous shower being rechargeable, it must be return to the supplier after receiving a new DAP.

Other containers can be recycled into materials or energy, depending on the material and the subsidiary treatment (possible waste code for sprays 16 05 05, and for plastics 15 01 02).

The amalgam of universal POLYCAPTOR® absorbent and DIPHOTERINE® solution can be used to produce energy by incineration as waste absorbents contaminated with non-hazardous substances (waste code 15 02 03).

The waste codes come from 2014/955/EU European Commission Decision.

In all cases, refer to the national or regional legislation in force concerning the waste treatment.

Do not dispose into the environment (sewers, rivers, soils).

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SECTION 14. TRANSPORT INFORMATION#

DIPHOTERINE® solution and pressureless packaging are not subject to transport regulations, only the following pressurised containers are regulated.

RID: Not used mode of transport.

ADN: Not used mode of transport.

ADR:

	Container type	
	MICRO DAP	MINI DAP
14.1. UN number	UN 1950	
14.2. UN proper shipping name	Aerosols	
14.3. Transport hazard class(es)	2	
Packing instructions	P207 LP200	

IMDG:

	Container type		
	MICRO DAP	MINI DAP	DAP
14.1. UN number	UN 1950		UN 1013
14.2. UN proper shipping name	Aerosols		Carbon dioxide
14.3. Transport hazard class(es)	2		2.2
Packing instructions	P207 LP200		P200

IATA (ICAO) :

	Container type		
	MICRO DAP	MINI DAP	DAP
14.1. UN number	UN 1950		UN 1013
14.2. UN proper shipping name	Aerosols, non-flammable		Carbon dioxide
14.3. Transport hazard class(es)	2.2		2.2
Packing instructions	203		200

14.4. Packing group:

Not applicable.

14.5. Environmental hazards:

DIPHOTERINE® solution presents no danger for the environment and it is not a marine pollutant.

14.6. Special precautions for user:

None.

14.7. Maritime transport in bulk according to IMO instruments:

Not applicable.

SECTION 15. REGULATORY INFORMATION#

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

DIPHOTERINE® solution is a class IIa medical device regulated in Europe by 93/42/EEC Directive Annex II, amended by 2007/47/EC Directive. As a result, and in accordance with European CLP Regulation (EC) No 1272/2008, this mixture is exempt from the SDS requirement.

This SDS has been written in accordance with European Regulation 2020/878/EC.

15.2. Chemical safety assessment:

Not applicable.

SECTION 16. OTHER INFORMATION[#]

Recommended use:

Use DIPHOTERINE® solution immediately and as first-line solution to wash eye or skin in cases of corrosive or irritant chemical splashes.

DIPHOTERINE® solution protocol and instructions for use are available for download on our website

www.prevor.com

Caution:

The disappearance of the pain sensation is not a sign of a complete washing. Follow the protocol and use the entire content of the device to reduce lesion development.

The possibility of a worsening incident depends on the chemical, its concentration and the time taken to treat it. A medical advice is always recommended.

In all cases, and particularly in the event of persistent discomfort or the presence of a foreign body, consult a specialist to verify that the washing has been carried out correctly.

Abbreviations:

CLP: Classification, Labelling and Packaging of substances and mixtures. It constitutes the European implementation of the UN's Globally Harmonized System (GHS).

EC: European Commission.

EEC: European Economic Commission.

EC₅₀: Half maximal Effective Concentration.

EU: European Union

GMT: Greenwich Mean Time.

LD₅₀: Median Lethal Dose.

MTT test: test carried out with tetrazolium salt reagent (MTT reagent)

SDS: Safety Data Sheet.

STOT: Specific Target Organ Toxicity.

ADN: International transport of goods by ways of inner navigation.

ADR: Accord for Dangerous goods by Road.

IATA (ICAO): International Civil Aviation Organization.

IMDG: International Maritime Dangerous Goods.

RID: Regulations concerning the International carriage of Dangerous goods by rail.

This document complements the user instructions but does not replace them. The information that is contained herein is based on our knowledge related to the product concerned on the date specified and is given in good faith. Moreover, the user attention is drawn to the possible risks involved when a product is used for purposes other than those for which it was intended.