	DIPHOTERINE®		Approved by: J. BLOMET	Safety Data Sheet
			1.93	Page number: 1/7
Process: REALIZE	File: FDS	Reference : GRV_QAL_FDS_Diphoterine_en	Effective Date: 19/05/2016	Update: 8

In accordance with European Regulation 1272/2008 (CLP) modifying European Regulation 1907/2006 (REACH)
SDS written in accordance with European Regulation 2015/830

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

1.1. Product identifier:

DIPHOTERINE®

Other denomination:

Aqueous solution containing amphoteric salts.

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:

Washing of ocular or cutaneous chemical splashes.

1.2.2. uses advised against:

DIPHOTERINE® solution is not recommended for the washing of splashes of hydrofluoric acid or fluorides in acidic medium.

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

PREVOR

Moulin de Verville

BP1

95760 VALMONDOIS

FRANCE

Telephone: +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 (business hours, GMT+1).

SECTION 2. HAZARDS IDENTIFICATION[#]

2.1. Classification of the mixture:

Non-hazardous mixture in accordance with Regulations 1272/2008/EC and 1907/2006/EC. DIPHOTERINE® solution does not require legally SDS (article 31 of the Regulation 1907/2006/EC modified by the article 57 of the Regulation 1272/2008/EC).

2.2. Label elements:

The mixture being non-hazardous, no danger and warning labelling is necessary.

2.3. Other hazards:

No other danger which may cause classification according to regulation in effect.

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS[#]

3.2. Mixture:

No hazardous ingredients.

Name	CAS N°	wp %
Amphoteric salts	proprietary	proprietary
Water	7732-18-5	balance

Impurities:

No hazardous impurities

SECTION 4. FIRST AID MEASURES[#]


4.1. Description of first aid measures:

DIPHOTERINE® solution is a class IIa medical device in Europe, without specific hazards and used in first aid in case of chemical contamination.

Victims of chemical exposure must seek advice from a specialist or receive medical attention. Bring a copy of the label and the SDS of the product which caused the injury to the physician or health professional.

The user protocol for DIPHOTERINE® solution is available and downloadable on our website www.prevor.com.

[#] Indicates data modified since the last update.

	DIPHOTERINE®		Approved by: J. BLOMET <i>J. Bl</i>	Safety Data Sheet
				Page number: 2/7
Process: REALIZE	File: FDS	Reference : GRV_QAL_FDS_Diphoterine_en	Effective Date: 19/05/2016	Update: 8

4.1.1. Inhalation:

This is not the major route of exposure. The product is non-toxic by inhalation. In case of adverse effects, consult a doctor.

4.1.2. Eye contact:

No specific hazards. For an ocular comfort, wash with the AFTERWASH II® solution or the WASHING SOLUTION after a primary washing with the DIPHOTERINE® solution.

4.1.3. Skin contact:

No specific hazards. For comfort, the skin can be rinsed with tap water.

4.1.4. Ingestion :

This is not the major route of exposure. The product is non-toxic by oral exposure. In case of adverse effects, consult a doctor.

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

No known unwanted effects.

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

No specific care. This mixture is a sterile medical device for temporary use. This mixture is not hazardous in itself. If necessary, apply a secondary treatment specific to the chemical involved.

In case of using DIPHOTERINE® solution for a chemical splash:

Responders should wear protection equipment appropriate to the chemical which contaminated the person.

SECTION 5. FIREFIGHTING MEASURES[#]

5.1. Extinguishing media:

Water spray, carbon dioxide, dry chemical, foam, dry powder or any "ABC" class device.

5.2. Special hazards arising from the substance or mixture:

Possible thermal decomposition above 100°C in toxic products: carbon monoxide and dioxide, nitrogen oxides and organic vapours.

5.3. Advice for firefighters:

In case of fire, wear self-contained breathing apparatus identical to that usually carried during any fire.

SECTION 6. ACCIDENTAL RELEASE MEASURES[#]

6.1. Personal precautions, protective equipment and emergency procedures:

In case of ocular contact and for an ocular comfort, wash with the AFTERWASH II® solution or the WASHING SOLUTION.

6.2. Environmental precautions:

Even if the mixture is not ecotoxic, limit discharges into the environment (sewers, rivers, soils).

6.3 Methods and material for containment and cleaning up:

No specific precautions. This product can be absorbed, for example, with an absorbent from PREVOR product range like POLYCAPTOR® polyvalent absorbent or TRIVOREX® polyvalent neutralizing absorbent.

6.4. Reference to other sections:

See sections 8 and 13.

SECTION 7. HANDLING AND STORAGE[#]

7.1. Precautions for safe handling:

No specific precautions.

7.2. Conditions for safe storage, including any incompatibilities:

Keep well closed in the original packaging. This product has a two years shelf-life if kept sealed in its original packaging. The portative eye wash can be kept six months after its preparation (cap opening), respecting the two years shelf-life.

When possible, store containers in a cool, dry location, and protect from frost or any source of intense heat (storage temperature between 2 and 50°C).

The ideal temperature of use is ambient temperature (between 15 and 35°C).


The product is stable in normal storage, handling and use.

Do not store in corrosive environment without protective case (wall-mounted stations or boxes).

7.3. Specific end use(s):

Washing of ocular or cutaneous chemical splashes.

[#] Indicates data modified since the last update.

	DIPHOTERINE®		Approved by: J. BLOMET <u>J. Blom</u>	Safety Data Sheet
				Page number: 3/7
Process: REALIZE	File: FDS	Reference : GRV_QAL_FDS_Diphoterine_en	Effective Date: 19/05/2016	Update: 8

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION[#]

8.1. Control parameters:

No known exposure limit.

8.2. Exposure control:

8.2.1. Appropriate engineering controls:

No specific precautions for the DIPHOTERINE® solution.

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

Eye/face protection:

No protection is required.

Skin protection:

Hand protection:

No protection is required.

Other:

No additional necessary protection.

Respiratory protection:

No protection is required.

Thermal risk:

No thermal risk with the DIPHOTERINE® solution.

Protection for the users:

No protection is required.

8.2.3. Environmental exposure controls:

The residue of chemical which contaminate the person and DIPHOTERINE® solution can retain the dangerous chemical's characteristics. So recover washing residue with, for example, an absorbent from PREVOR product range like POLYCAPTOR® polyvalent absorbent, TRIVOREX® polyvalent neutralizing absorbent, ACICAPTAL® neutralizing absorbent specific to acids or BASICAPTAL® neutralizing absorbent specific to bases.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES[#]

9.1. Information on basic physical and chemical properties:

a) Appearance (at 20°C):

Clear and colourless liquid.

b) Odour:

Odourless.

c) Odour detection threshold:

Non applicable because the mixture is odourless.

d) pH:

pH from 7.2 to 7.7 (at 20°C).

e) Melting point / freezing point:

-1°C.

f) Initial boiling point and boiling range:

100°C.

g) Flash point:

Non applicable because the mixture is non-flammable.

h) Evaporation rate:

1 (water = 1).

i) Flammability (solid, gas):

The mixture is non-flammable.

j) Upper / lower flammability or explosive limits:

Non applicable because DIPHOTERINE® solution is not flammable.

k) Vapour pressure:

18 mm Hg (at 20°C).



l) Vapour density:

Non determined.

m) Relative density:

1.032 (density = 1.032 g.cm⁻³).

[#] Indicates data modified since the last update.

	DIPHOTERINE®		Approved by: J. BLOMET	Safety Data Sheet
				Page number: 4/7
Process: REALIZE	File: FDS	Reference : GRV_QAL_FDS_Diphoterine_en	Effective Date: 13/05/2016	Update: 8

n) Solubility (ies):

Miscible in water.
Slightly miscible in organic solvents.

o) Partition coefficient n-octanol/water:

Miscible in water.

p) Auto-ignition temperature:

Non applicable because the mixture is non-flammable.

q) Decomposition temperature:

Possible thermal decomposition above 100°C.

r) Viscosity:

Similar to the viscosity of water.

s) Explosive properties:

No explosive property.

t) Oxidizing properties:

No oxidising property.

SECTION 10. STABILITY AND REACTIVITY[#]

10.1. Reactivity:

The mixture is non-reactive.

10.2. Chemical stability:

Stable in the conditions recommended for storage.

10.3. Possibility of hazardous reactions:

None known to date (no hazardous polymerization, no decomposition, no condensation and no self-reactivity expected).

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 drill or expose to sunlight (avoid temperature higher than 50°C). For DAP (autonomous portative shower) avoid temperature higher than 60°C.

10.5. Incompatible materials:

None known to date.

10.6. Hazardous decomposition products:

Possible thermal decomposition above 100°C with liberation of carbon monoxide and dioxide, nitrogen oxides and organic vapours.

SECTION 11. TOXICOLOGICAL INFORMATION[#]

The biological evaluation of medical device is described in norm ISO 10993-1. Considering the nature and duration of body contact with DIPHOTERINE® solution, the biological effects to be tested are: cytotoxicity, sensitization and irritation. Supplementary tests, recommended by norm ISO 10993-1 for other types of body contacts, or longer contact duration, were also performed.

11.1. Information on toxicological effects:

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 (Ames test negative).

f) Carcinogenicity:

Not determined.

[#] Indicates data modified since the last update.

	DIPHOTERINE®		Approved by: J. BLOMET <u>1.32</u>	Safety Data Sheet
				Page number: 5/7
Process: REALIZE	File: FDS	Reference : GRV_QAL_FDS_Diphoterine_en	Effective Date: 19/05/2016	Update: 8

g) Reproductive toxicity:

Not determined.

h) Specific target organ toxicity – single exposure:

Not determined.

i) Specific target organ toxicity – repeated exposure:

Not determined.

j) Aspiration hazard:

Not determined.

k) other informations:

Cytotoxicity: non-cytotoxic (MTT test on fibroblasts).

Local skin tolerance (occlusive test on healthy volunteers): non-irritant.

Local skin tolerance on damaged skin / skin healthy (non-occlusive and semi-occlusive test): no irritant or toxic effect (test on rabbit).

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:

Non persistent. DIPHOTERINE® solution is stable, but will decompose into simple salts in the environment.

12.3. Bioaccumulative potential:

DIPHOTERINE® solution is not bioaccumulable (miscible in water and slightly miscible in organic solvents).

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. Other adverse effects:

No known adverse effects known to date.

SECTION 13. DISPOSAL CONSIDERATIONS[#]

13.1. Waste treatment methods:

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

Autonomous portative shower (DAP) being rechargeable, it must be return to the supplier after reception

of the new one. Others containers can be used to produce energy by incineration (waste code 15 01 02).

The amalgam of absorbent and DIPHOTERINE® solution can be treated by incineration like absorbents waste contaminated with non-dangerous substances (waste code 15 02 03).

The residue of chemical which contaminate the person and DIPHOTERINE® solution can retain the dangerous chemical's characteristics. So you have to treat this residue like the chemical or like an aqueous liquid waste contaminated with dangerous substances (waste code 16 10 01*).

The amalgam of this residue and an absorbent from PREVOR products' range can also remained dangerous. This amalgam can be used to produce energy by incineration like absorbents waste contaminated with dangerous substances (waste code 15 02 02*).

The waste codes come from Decision n° 2014/955/EU to the European Commission.

Do not discharge into the environment.

In all cases, we must refer to national or regional legislation on waste treatment.

[#] Indicates data modified since the last update.



DIPHOTERINE®

Approved by: J. BLOMET

Safety Data Sheet

L. BL

Page number: 6/7

Process:
REALIZEFile:
FDSReference :
GRV_QAL_FDS_Diphoterine_enEffective Date:
19/05/2016Update:
8

SECTION 14. TRANSPORT INFORMATION[#]

There is no transport regulation to be applied to the DIPHOTERINE® solution.

RID: Mode of transport don't used.

ADN: Mode of transport don't used.

ADR:

	Container type	
	MICRO DAP	MINI DAP
14.1. UN number	UN 1950	UN 1950
14.2. UN proper shipping name	Aerosols, non-flammable	Aerosols, non-flammable
14.3. Transport hazard class(es)	2,2	2,2
Packing instructions	P207	P207
	LPO2	LPO2

IMDG:

	Container type		
	MICRO DAP	MINI DAP	DAP
14.1. UN number	UN 1950	UN 1950	UN 1013
14.2. UN proper shipping name	Aerosols, non-flammable	Aerosols, non-flammable	Carbon dioxide
14.3. Transport hazard class(es)	2,2	2,2	2,2
Packing instructions	P207	P207	P200
	LPO2	LPO2	

IATA (ICAO) :

	Container type		
	MICRO DAP	MINI DAP	DAP
14.1. UN number	UN 1950	UN 1950	UN 1013
14.2. UN proper shipping name	Aerosols, non-flammable	Aerosols, non-flammable	Carbon dioxide
14.3. Transport hazard class(es)	2,2	2,2	2,2
Packing instructions	203	203	200

14.4. Packing group:

Non applicable.

14.5. Environmental hazards:

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

14.6. Special precautions for user:

No special precautions to be taken by the user.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:

As the products are delivered conditioned, this subsection is not applicable.

SECTION 15. REGULATORY INFORMATION[#]

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



Classified as non-hazardous in accordance with the European Regulations concerning classification, labelling and packaging of substances and mixtures: Regulation 1272/2008/EC (CLP) modifying Regulation 1907/2006/EC (REACH).

SDS written in accordance with Regulation 2015/830/EC, modifying Regulations 453/2010/EC and 1907/2006/EC concerning requirements for the compilation of SDS.

15.2. Chemical Safety Assessment:

Non applicable.

[#] Indicates data modified since the last update.

	DIPHOTERINE®		Approved by: J. BLOMET	Safety Data Sheet
				Page number: 7/7
Process: REALIZE	File: FDS	Reference : GRV_QAL_FDS_Diphoterine_en	Effective Date: 29/05/2016	Update: 8

SECTION 16. OTHER INFORMATION[#]

Recommended use:

Use DIPHOTERINE® solution immediately and as primary action to wash eye or skin in cases of chemical splashes (acids, bases, oxidizers, reducing agents, chelators or solvents).

The user protocol for DIPHOTERINE® solution is available and downloadable on our website

www.prevor.com.

Caution:

- 1 -In case of persistent discomfort or foreign bodies after washing, it is recommended to consult a specialist.
- 2 -In case of splash of hydrofluoric acid or fluoride compound in acidic medium, it is recommended to use HEXAFLUORINE® solution as primary action and to consult a doctor.
- 3 -In any case, ensure that washing has been done correctly and apply the current protocol advised by the medical officer.

Abbreviations:

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

REACH: Registration, Evaluation, Authorisation and restriction of Chemicals.

EC: European Commission.

EU: European Union.

SDS: Safety Data Sheet.

GMT: Greenwich Mean Time.

CAS n°: Chemical Abstract Service (registry) number.

wt. %: weight percent. It is the ratio of the mass of one element to the total mass of a compound.

"ABC" class device: extinguisher for A class fire (coming from solid materials containing organic materials such as wood, cotton, paper, grass, plastic), B class fire (coming from flammable liquids) or C class fire (coming from gas).

MTT test: test performed with tetrazolium salt reagent (MTT reagent).

LD₅₀: Lethal Dose. Median lethal dose of a substance, or the amount required to kill 50 % of a given test population.

EC₅₀: half maximal Effective Concentration. It refers to the concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum after a specified exposure time.

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

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

ADR: Accord for Dangerous goods by Road.

IMDG: International Maritime Dangerous Goods.

IATA (ICAO): International Civil Aviation Organization.

SDS update:

DIPHOTERINE® solution SDS is updated with an evolution in regulations, with a new technical data or when the annual review of regulation, scientific information and production data induce a modification in the risk assessment of DIPHOTERINE® solution.

This sheet complements the technical sheets but does not replace them. The information that is contained herein is based on the state of our knowledge related to the product concerned at the date of issue and is given in good faith. Moreover, the user's attention is drawn to the possible risks incurred by using the product for any other use than that for which it was intended.

[#] Indicates data modified since the last update.