In accordance with European Regulation 1272/2008 (CLP)
SDS read in accordance with European Regulation 2015/830 (REACH)

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

1.1. Product identifier:

Afterwash II®

Other denomination:

Ophthalmic solution isotonic to the cornea.

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:

Secondary eyewash to restore ocular physiological balance after chemical splash decontamination.

1.2.2. uses advised against:

Afterwash II® solution is not recommended for the washing of ocular chemical splashes.

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

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 Regulation 1272/2008/EC.
Afterwash II® solution is a class IIa medical device in Europe. The mixture being non-hazardous, it does not require legally SDS according to the article 31 of the Directive 1907/2006 and seen the modifications of this article in the Directive 1272/2008 (article 57).

2.2 Label elements:

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

2.3. Other hazards:

No other danger known to date.

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS#

3.2. Mixture:

No hazardous ingredients.

Name	CAS N°	wp %
Sodium chloride	7647-14-5	1,4
Amphoteric and chelating salts	proprietary	proprietary
Water	7732-18-5	balance

Impurities:

No hazardous impurities

SECTION 4. FIRST AID MEASURES#

4.1. Description of first aid measures:

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. This product is intended for ocular use.

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. Non-toxic product 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 a temporary ocular use. This mixture is not hazardous in itself.

SECTION 5. FIREFIGHTING MEASURES#

This product is non-inflammable and non-combustible.

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 :

Thermal decomposition above 240°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:

No specific precautions with Afterwash II® 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 save handling:

No specific precautions.

7.2. Conditions for safe storage, including any incompatibilities:

Keep well closed in the original packaging. This product has two years shelf-life if kept sealed in its original packaging.

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.

7.3. Specific end use(s):

Secondary eyewash to restore ocular physiological balance after chemical splash decontamination.

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 Afterwash II® 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 Afterwash II® solution.

Protection for the users:

No protection is required.

8.2.3. Environmental exposure controls:

Recover washing residue with, for example, an absorbent from PREVOR product range like Polycaptor® polyvalent absorbent or Trivorex® polyvalent neutralizing absorbent.

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 6 to 8 (at 20°C).

e) Melting point / freezing point:

-1°C.

f) Initial boiling point and boiling range:

99°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 Afterwash II® solution is not flammable.

k) Vapour pressure:

18 mm Hg (20°C).

l) Vapour density:

Non determined.

m) Relative density:

1.008 $g.cm^{-3}$.

n) Solubility (ies):

100 % miscible in water.

Slightly miscible in organic solvents.

o) Partition coefficient n-octanol/water:

100 % miscible in water.

p) Auto-ignition temperature:

Non applicable because the mixture is non-flammable.

q) Decomposition temperature:

Thermal decomposition above 240°C.

r) Viscosity:

Similar to the viscosity of water.

s) Explosive properties:

No explosive property.

t) Oxidizing properties:

No oxidising property.

9.2. Other information:

None known to date.

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.

10.5. Incompatible materials:

None known to date.

10.6. Hazardous decomposition products:

Thermal decomposition above 240°C with liberation of carbon monoxide and dioxide, nitrogen oxides and organic vapours.

SECTION 11. TOXICOLOGICAL INFORMATION#

11.1. Information on toxicological effects (all tests for this section are performed on similar molecule):

a) Acute toxicity:

LD_{50} (oral in rat) > 2000 $mg.kg^{-1}$.

b) Skin corrosion / irritation:

Non-irritant and non-corrosive (*in-vitro* tests Dermal Irritection® 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.

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:

No local effects on the respiratory tract during ingestion or aspiration other than those that can occur with water.

k) other informations:

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#

Afterwash II® solution is not harmful if released into the environment.

12.1. Toxicity (all tests are performed on similar molecule):

12.1.1. Microtoxicity:

No known adverse effects on *Photobacterieum phosphoreum* :
EC_{50} 15 min at 8.63 % (or at 5136 $mg.L^{-1}$).
EC_{50} 30 min at 9.8 % (or at 5832 $mg.L^{-1}$).

12.1.2. Aquatic toxicity:

No known adverse effects on *Daphnia Magna* :

EC_{50} 24h at 9.5 % (or at 5664 $mg.L^{-1}$).

12.2. Persistence and degradability:

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

12.3. Bioaccumulative potential:

Afterwash II® solution is not bioaccumulable (log Ko/w: 100 % miscible in water).

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).
Containers can be used to produce energy by incineration (waste code 15 01 02).
The amalgam of absorbent and Afterwash II® solution can be treated by incineration like absorbents waste contaminated with non-dangerous substances (waste code 15 02 03).
Do not discharge into the environment.
In all cases, we must refer to national or regional legislation on waste treatment.

SECTION 14. TRANSPORT INFORMATION#

14.1. UN number:

Non applicable (see section 2).

14.2. UN proper shipping name:

Non applicable.

14.3. Transport hazard class(es):

There is no regulation to be applied to transport products containing Afterwash II® solution.
RID: Non applicable.
ADN: Non applicable.
ADR: Non applicable.
IMDG: Non applicable.
IATA (ICAO): Non applicable.

14.4. Packing group:

Non applicable.

14.5. Environmental hazards:

Afterwash II® 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 labelling of hazardous mixtures: regulations 1272/2008/EC (CLP).
Regulatory reference: Regulation 2015/830/EC (REACH).
Regulation 2015/830/EC modifying regulation n° 453/2010/EC and n° 1907/2006/EC of European Parliament and Council concerning recording, evaluation and authorization of chemical substances, as well as limitations applicable to these substances (REACH).

15.2. Chemical Safety Assessment:

Non applicable.

SECTION 16. OTHER INFORMATION#

Recommended use:

Afterwash II® solution is used after a primary eyewash chemical decontamination with Diphoterine®, Previn solutions. This aqueous solution, isotonic to the cornea, can restore faster and more comfortably the physiological balance of the eye.

Afterwash II® solution can also be used to wash chemically inert dust present on the surface of the eye.

Caution:

1 - In case of persistent discomfort or foreign bodies after washing, it is recommended to consult a specialist.

2 - In case of chemical dust or splash (acids, bases, oxidizers, reducing or solvents), it is recommended to use Diphoterine® solution immediately as primary action and to consult a doctor.

3 - Diphoterine has limited efficiency on hydrofluoric acid (HF) and fluorides in acidic environment.

4 - 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 substance 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.
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).
In-vitro MTT test: test performed with tetrazolium salt reagent (MTT reagent).
LD_{50}: Lethal Dose. Median lethal dose of a substance, or the amount required to kill 50 % of a given test population.
EC_{50}: 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.

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.