

AGUETTANT VERSOL®

TECHNICAL FILE

Sterile Distilled Water, Sodium Chloride 0.9%

For irrigation



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CE0459
Doc 175/06
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1. GENERAL DESCRIPTION OF VERSOL® PRODUCTS

Versol® bottles are medical devices which are covered by EEC Directive 93/42 of 14/6/93 pertaining to medical devices and the book V bis CSP (code de la santé publique, French Health public code) for which they are applicable.

Versol® (Sodium Chloride 0.9%, Sterile Distilled Water or Ringer) are designed for medical and surgical applications.

They are sterile, apyrogenic solutions mainly designed for the rinsing and irrigation of wounds (see § 1.3).

1.1. COMPOSITION

Sodium Chloride 0.9%

- sodium chloride 9 g,
- water for injections q.s. 1000 ml

Sterile Distilled Water

- water for injections q.s. 1000 ml

1.2. CONTAINER

Versol® bottles are made of polypropylene.

Polypropylene is transparent so the solution inside the bottle can be visually checked. Polypropylene is water-tight, light, unbreakable and does not react with the solutions. The part of the cap in contact with the solution (plug) is also polypropylene.

The bottle has a lip to prevent drips and protect against any of the fluid running down the outside. The bottle is graduated and is made in a square shape to make it easier to store and hold. At the base of the cap is a tamper evident seal to detect tamper evidence.

For product differentiation, the shell, that part of the cap not in contact with the solution, is coloured as follows:

- Blue for Water
- Green for Sodium Chloride 0.9%

Pour bottles are available in two volumes: 500 ml and 1000 ml.

The batch number and the expiry date are embossed in the polypropylene during bottle moulding.

1.3. INDICATIONS & RECOMMENDED APPLICATIONS

Versol® Sterile Distilled Water, pyrogen free

Rinsing and irrigation of wounds ♦ the generation of aerosols ♦ humidification: fitted directly on certain humidification systems preventing all contamination due to transfer ♦ wetting: can be directly fitted to certain wetting systems thereby eliminating the possibility of contamination during the transfer of solutions ♦ the rinsing of surgical instruments ♦ rinsing in full disinfection protocols for surgical equipment.

Versol® Sterile Sodium Chloride 0.9% in distilled water and pyrogen free

Rinsing and irrigation of wounds ♦ wetting ♦ rinsing operations which require a sterile, isotonic solution.

1.4. DIRECTIONS & PRESENTATIONS

- DIRECTIONS: Check before use: the clearness of the solution, the integrity of the bottle, the safety seal, and the capping (a Viskering seal not firmly attached to the base of the cap indicates that the bottle has been opened). Do not re-use a bottle which has already been opened.

- PRESENTATIONS: box of 10 x 1000 ml bottles
 box of 20 x 500 ml bottles

- STABLE FOR: 2 years.

1.5 LABELING

Products

1000 ml

WATER FOR IRRIGATION
VERSOL®

1000 ml **H₂O**

Twist cap anticlockwise to break seal and open

Not for injection.
For irrigation use only.
Pyrogen Free.
Use once only and discard remainder.
Use only if seal is intact.
Do not heat above 40° before use.

Laboratoire Aguettant
1, rue Alexander Fleming - 69007 Lyon - France

AGUETTANT

CE0459
STERILE
2
40°C

100069-06/03
7 3 3 9 5 8 5 2 *

SODIUM CHLORIDE 0.9% w/v FOR IRRIGATION
VERSOL®

1000 ml **NaCl**

Twist cap anticlockwise to break seal and open

Not for injection.
For irrigation use only and as eye irrigation. Pyrogen Free.
Use once only and discard remainder.
Use only if seal is intact.
Do not heat above 40° before use.

Laboratoire Aguettant
1, rue Alexander Fleming - 69007 Lyon - France

AGUETTANT

CE0459
STERILE
2
40°C

100071-06/03
7 3 3 9 5 8 1 7 *

500 ml

WATER FOR IRRIGATION
VERSOL®

500 ml **H₂O**

Twist cap anticlockwise to break seal and open

Not for injection.
For irrigation use only.
Pyrogen Free.
Use once only and discard remainder.
Use only if seal is intact.
Do not heat above 40° before use.

Laboratoire Aguettant
1, rue Alexander Fleming - 69007 Lyon - France

AGUETTANT

CE0459
STERILE
2
40°C

100068-06/03
7 3 3 9 5 8 4 6 *

SODIUM CHLORIDE 0.9% w/v FOR IRRIGATION
VERSOL®

500 ml **NaCl**

Twist cap anticlockwise to break seal and open

Not for injection.
For irrigation use only and as eye irrigation. Pyrogen Free.
Use once only and discard remainder.
Use only if seal is intact.
Do not heat above 40° before use.

Laboratoire Aguettant
1, rue Alexander Fleming - 69007 Lyon - France

AGUETTANT

CE0459
STERILE
2
40°C




100070-06/03
7 3 3 9 5 8 2 3 *


Boxes

**SODIUM CHLORIDE
0.9% w/v FOR IRRIGATION**
VERSOL®

NaCl

Twist cap anticlockwise
to break seal and open
Not for injection.
For irrigation use only and as eye irrigation.
Pyrogen Free. Use once only and discard remainder.
Use only if seal is intact.
Do not heat above 40° before use.

CE0459
STERILE 




AGUETTANT
Laboratoire Aguettant
1, rue Alexander Fleming
69007 Lyon - France




LOT




**WATER
FOR IRRIGATION**
VERSOL®

H₂O

Twist cap anticlockwise
to break seal and open
Not for injection.
For irrigation use only. Pyrogen Free.
Use once only and discard remainder.
Use only if seal is intact.
Do not heat above 40° before use.

CE0459
STERILE 




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69007 Lyon - France

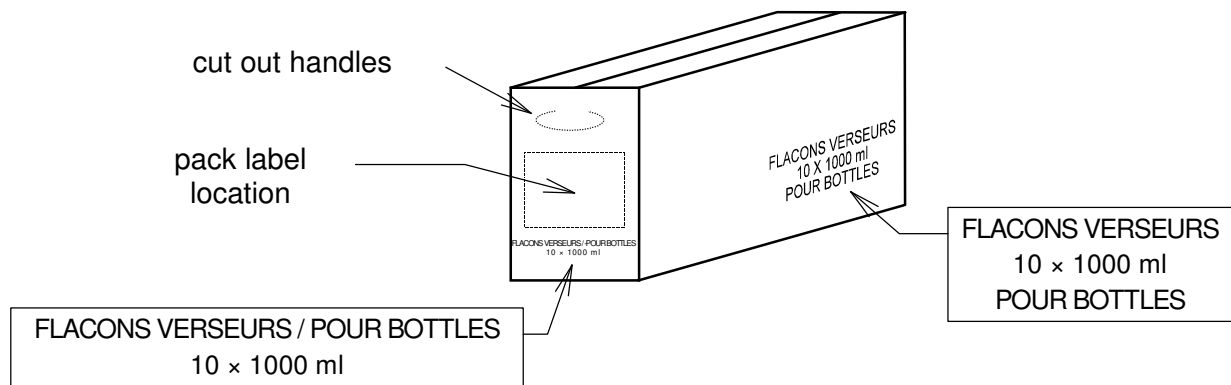
LOT



1.6. MULTI PACK

Type of bottle	Nber of bottles per carton	Dimensions (in mm)			Cut out handles	Carton Quality	Printing colour
		Length	Width	Height			
500 ml	20	434	172	275	yes	PC 20 kg	Pantone blue(300)
1000 ml	10	434	175	226	yes	PC 20 kg	Pantone blue (300)

These multi packs are as follows:



2. VERSOL® MANUFACTURE AND QUALITY CONTROL

2.1. CONTROL OF RAW MATERIAL

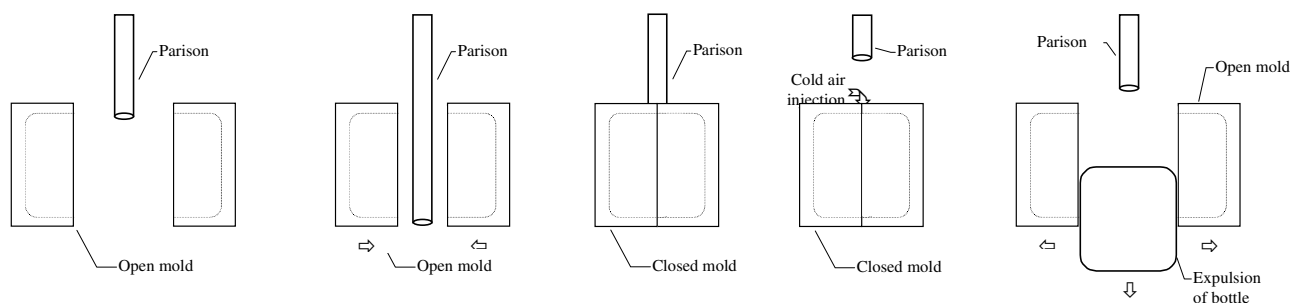
All raw materials for the Versol® solutions: water for injection and sodium chloride are inspected and comply with relevant European Pharmacopoeia Monographs.

2.2. MANUFACTURE OF POLYPROPYLENE BOTTLES

Versol® bottles (250 ml, 500 ml and 1000 ml) are made of polypropylene in an extrusion-blowing process performed in a Clean Area.

The Batch Number and Expiration Date are engraved on the base of the bottle during manufacture.

An outline of the extrusion-blowing process:



2.3. BOTTLE FILLING AND QUALITY CONTROL PROCEDURES

Bottle closure is carried out by cap installation immediately after filling.

From manufacture of the bottle to installation of the cap, all operations are carried out in a controlled atmosphere (Class 10 000) and the bottles are permanently protected by class 10 000 laminar flow throughout the manufacturing process.

Functional and metrological controls are carried out at the beginning of each batch, and regularly throughout manufacturing:

- Empty bottle controls
 - the internal diameter of the neck,
 - thickness,
 - weight,
 - batch number and expiry date.

- Full bottle controls
 - o The colour of the cap,
 - o The unscrewing torque of the cap,
 - o The presence of visible particles,
 - o The extractible volume,
 - o The resistivity of the solution.

- the presence, and colour of the cap.

2.4. STERILIZATION OF BOTTLES

The bottles are autoclave-sterilized.

After packaging, operatives pick sample bottles and send them to the laboratory to be checked for sterility. Details are appended to the Batch File to show that the bottles have been sterilized.

2.5. FINISHED PRODUCT QUALITY CONTROL

The results of these tests are recorded, and physical, biological and bacteriological tests are carried out by the Test Laboratory. Finished product sterility is checked according to currently applicable European Pharmacopeia specifications.

The checking procedures cover:

- the sealing of the boxes,
- pallet number,
- the printing and accuracy of the box label,
- the number of bottles per box,
- the appearance and water-tightness of the bottles,
- that the embossing of the Batch Number and Expiration Date is within specifications,
- that cap is present,
- the printing and accuracy of the bottle label.

The results of all these checking procedures are recorded in a Test Certificate which is appended to the Batch File. A copy of this Test Certificate is sent to customers on request.

3. PHYSICAL AND CHEMICAL STABILITY OF VERSOL® BOTTLES

3.1. STABILITY TESTS & BIOCOMPATIBILITY OF MATERIALS

Stability

The stability of batches of Versol® bottles containing either Sodium Chloride 0.9% or Sterile Distilled Water was investigated at room temperature (25°C) for 24 months and 40°C for 6 months.

Physical and chemical and bacteriological tests performed on these bottles were the same as those usually carried out on the finished product.

On one batch volume and per product, the following is carried out:

- Research of possible salting-out in the solution of bottle polypropylene additives, or polypropylene of the plug of the cap (only part of the cap in contact with the solution),
- An evaporation study.

The results showed that Versol bottles are stable for 2 years in all test conditions in that they remain within the specifications fixed for the finished product.

3.2. RESISTANCE TO HEATING IN A MICROWAVE OVEN

Versol® bottles were heated in a microwave oven in order to check whether they became deformed as a result of such treatment.

EQUIPMENT:

- microwave oven (model MS-192A [LGEFS] 19L, 800W)
- thermometer (ref. Checktemp1A [Polylabo], from -50° to 150°C)
- 4 x 1-litre Versol bottles containing Water for Injection (Batch n° F-1976)
- 1 x 500-millilitre Versol bottle containing Water for Injection (Batch n° F-1968)

METHODS

The power output of the microwave oven was set to High, i.e. **800W**. The test bottle was laid on the oven's revolving plate and timer was set to a series of different times.

After heating, the following parameters were investigated:

- deformation of the bottle,
- how easy it was to screw and unscrew the cap.

Then the bottle was opened and the temperature of the water inside measured with a thermometer. Finally, the bottle was closed again and its water-tightness checked by applying pressure to the walls of the bottle (no liquid should escape).

RESULTS

Room temperature: 22.5 °C		oven power setting (W)	oven timer setting (min)	temperature of water (°C)	deformation	screwing/unscrewing of cap	water-tightness
VERSOL 1-litre	bottle 1	800	3.5	69	Within specs.	Within specs.	Within specs.
	bottle 2		3	66	Within specs.	Within specs.	Within specs.
	bottle 3		2	44	Within specs.	Within specs.	Within specs.
	bottle 4		1.5	41	Within specs.	Within specs.	Within specs.
VERSOL 500ml	bottle 1		3	77	Within specs.	Within specs.	Within specs.

CONCLUSIONS

In the conditions of the test (an oven power of 800 W and heating cycles of between 1.5 and 3.5 minutes resulting in a maximum water temperature of 66 °C), neither the 1-liter nor the 500 ml Versol bottles underwent any deformation. To attain a temperature of 37 °C, heating the bottle in an 800 Watt microwave oven for a period below 1.5 minutes is recommended.

4. NORMS APPLIED

REFERENCES

- Directive 93/42/EEC of 14/6/93 pertaining to medical devices.
- Book V bis CSP (code de la santé publique, French Health public code)

NORMS APPLIED

- NF EN 46002 (December 1996): Quality Systems - Medical Devices.
- ISO 9001 (December 2000) : Management Quality Systems.
- NF EN 1441 (April 1998) : Medical Devices - Risk analysis
- Federal Standard FS 209-E (June 1988): Clean room and work station requirements, controlled environment.
- NF EN 980 (August 1996): Graphic symbols used for the labelling of medical devices.
- EN 1041 (April-98): Information supplied by the manufacturer with the medical devices.
- NF EN 556 (February 1995): Requirements for sterile labelled medical devices.
- NF EN 554 (October-94): Sterilisation of medical devices - Validation and routine test of water steam sterilisation.

OTHERS:

- Currently applicable European Pharmacopeia.
- Currently applicable Good Manufacturing Practices.
- Currently applicable UPS (American Pharmacopeia)

5. EC CERTIFICATE
EC ATTESTATION OF COMPLIANCE



Le progrès, une passion à partager

Certification
Médical-Santé

ATTESTATION/ CERTIFICATE N° 10471 rev.1

Délivrée à Paris le 12 juin 2009

Issued in Paris on June 12th, 2009

ATTESTATION CE / EC CERTIFICATE

Approbation du Système d'Assurance Qualité de la Production / Approval of Production Quality Assurance System

ANNEXE V point 3 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX V section 3 DIRECTIVE 93/42/EEC concerning medical devices

Fabricant (nom et adresse) / Manufacturer (name and address)

LABORATOIRE AGUETTANT

1 rue Alexander Fleming,

69007 LYON 07 FRA

Catégorie du(des) dispositif(s) / Device(s) category

**Solutions stériles conditionnées en flacons versables destinées au rinçage
et à l'irrigation des plaies (eau ou chlorure de sodium 0,9% ou ringer).**

*Sterile solutions in pouring bottles for rinsing
and irrigation of wounds (water or chloride of sodium 0.9 % or ringer).*

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé J100532-R, le système d'assurance qualité - pour la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe V point 3 de la Directive 93/42/CEE.

LNE/G-MED certifies that, on the basis of the results contained in the file referenced J100532-R, the quality system - for manufacturing and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex V section 3.

Début de validité / Effective date : June 13th, 2009 (included)

Valable jusqu'au / Expiry date : June 12th, 2012 (included)



VO 04-07-2007

LNE - 10471 rev. 1
Renouvelle le certificat 0485/B5/01

On behalf of the Deputy Director
Thierry THOMAS
G-MED Certification Division Manager

Laboratoire national de métrologie et d'essais • Établissement public à caractère industriel et commercial
LNE/G-MED • Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 • Tél. : 01 40 43 37 00 • Fax : 01 40 43 37 37 • www.lne.fr • www.gmed.fr



DECLARATION CE DE CONFORMITE

EC DECLARATION OF CONFORMITY

Je, soussigné Ariel AGUETTANT, Président Directeur Général du Laboratoire AGUETTANT, 1 rue Alexander Fleming, 69007 LYON, assure et déclare que les solutions stériles conditionnées en flacons versables, dispositifs médicaux de classe IIa utilisés pour le rinçage et l'irrigation des plaies (eau, chlorure de sodium 0,9% et ringer, 250, 500 et 1000 ml), satisfont aux dispositions de la Directive 93/42/CEE du 14 juin 1993 et du livre V bis du Code de la Santé publique qui lui sont applicables.

Cette déclaration s'appuie sur le dossier technique constitué conformément à l'annexe VII de la directive 93/42/CEE et sur l'attestation de conformité à l'annexe V de la directive 93/42/CEE délivrée par le G-MED (attestation N°0485/B5/1), organisme notifié français N°0459

I, undersigned, Ariel AGUETTANT, Chairman of AGUETTANT Laboratory, 1 rue Alexander Fleming, 69007 LYON, hereby, declare under my responsibility that sterile solutions in pouring bottles, medical devices of class IIa for rinsing and irrigation of wounds (water, sodium chloride 0,9% and ringer, 250, 500 et 1000ml), complie with the requirements of the European Directive 93/42/EEC and the book V bis CSP (code de la santé publique, French Health public code) for the which they are applicable.

This declaration is based on the technical file assembled according to Annex VII of the Directive 93/42/EEC and on the assessment of conformity of the quality system - for manufacturing and final testing - to Annex V of the Directive 93/42/EEC provided by G-MED, (Attestation N°0485/B5/1), French notified body N° 0459.

Fait à Lyon, le 9 janvier 2006.

Ariel AGUETTANT
Président Directeur Général
Chairman

Laboratoire AGUETTANT

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