

# virox

Swiss  
chemi

## STERIZOL

Virox STERIZOL Antiseptic solution for disinfecting and cleansing traumatic and surgical wounds and burns. STERIZOL Sachets is a broad-spectrum Aqueous antiseptic Solution that are designed to clean and disinfect traumatic and surgical wounds and burns. It is also effective for swabbing during obstetric procedures and during dressing changes.

Virox STERIZOL Sachet contains 0.05% chlorhexidine gluconate, an antimicrobial agent that is effective against a wide range of gram-positive and gram-negative bacteria that may be present on the skin Sterizol is disinfectant with bactericidal properties that helps to cleanse the skin and wound.

The Light pink-coloured aqueous solution is available in clear plastic sachets over wrapped in heat sealed sterile pouches.

Provides antimicrobial protection against a wide range of common organisms

Helps to support hospital infection control protocols

solution that supports the aseptic process and neonates

Yellow coloured for easy identification and to avoid misuse

25 ml aqueous solution contains  
chlorhexidine gluconate 0.05% w/v



SCCHC0025 Pack of 20 sachets

Swiss Chemi Pvt. Ltd

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# Safety Data Sheet

## VIROX STERIZOL

### Section 1. Identification

Product Identifier **VIROX-STERIZOL**

Manufacturer Stock Numbers **SCCHC\*\*\*\*\* ,**

Recommended use **Skin Disinfection**

Contact Address **Swiss chemi Pvt Ltd  
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Website **www.swisschemi.com**

### Section 2. Hazards Identification

Classification **NON FLAMMABLE LIQUIDS -**

Signal Word **DANGER**

Pictogram



### Section 3. Ingredients

| CAS        | Ingredient Name         | Weight % |
|------------|-------------------------|----------|
| 18472-51-0 | Chlorhexidine gluconate | < 0.05%  |
| 7732-18-5  | Water                   |          |
| 1310-73-2  | Ph Balancer             |          |

### Section 4. First-Aid Measures

General Advice: Show this safety data sheet to the doctor in attendance.

|                                  |  |
|----------------------------------|--|
| Eye Contact:                     | Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if applicable, and continue flushing. If symptoms persist, call a physician. |
| Skin Contact:                    | In the case of skin irritation or allergic reactions see a physician.  |
| Inhalation:                      | Move to fresh air. Get medical attention immediately if symptoms occur. If breathing has stopped, contact emergency medical services immediately and give artificial respiration.            |
| Ingestion:                       | If swallowed do not induce vomiting. Clean mouth with water and afterwards drink plenty of water. Never give anything by mouth to an unconscious person. Consult a physician if necessary.   |
| Most important symptoms/effects: | Burning sensation. Itching. Rashes. Hives. Coughing and/or wheezing. May cause breathing difficulties if inhaled.  |
| Note to Physician:               | Treat symptomatically  |

## Section 5. Fire Fighting Measures

|  |   |
|--|---|
| Suitable Extinguishing Media                         | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Dry chemical. Carbon dioxide (CO <sub>2</sub> ). Water spray.   |
| Unsuitable Extinguishing Media                       | Caution: Use of water spray when fighting fire may be inefficient.  |
| Specific hazards arising from the chemical:          | Risk of ignition. Keep product and empty container away from heat and sources of ignition. In the event of fire, cool tanks with water spray. Vapors may form explosive mixtures with air. Most vapors are heavier than air. They will spread along ground and collect in low or confined areas (sewers, basements, tanks). |
| Uniform Fire Code:                                   | Nil   |
| Hazardous combustion products:                       | Carbon oxides.  |
| Explosion data:                                      | Sensitivity to Mechanical Impact: No<br>Sensitivity to Static Discharge: Yes  |
| Protective equipment & precautions for firefighters: | As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.  |

## Section 6. Accidental Release Measures

|  |  |
|--|--|
| Personal precautions, protective equipment and emergency procedures: | Avoid contact with eyes and clothing. Ensure adequate ventilation. Keep people away from and upwind of spill/leak. See section 8 for more information. Eliminate all ignition sources (no smoking, flares, sparks or flames in immediate area). Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Do not touch or walk through spilled material. |
| Other Information:   | Refer to protective measures listed in sections 7 and 8. Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.   |
| Methods for containment:   | Prevent further leakage or spillage if safe to do so. Do not touch or walk through spilled material. A vapor suppressing foam may be used to reduce vapors. Dike far ahead of spill to collect runoff water. Keep out of drains, sewers, ditches and waterways.  |

Methods for cleaning up: Take precautionary measures against static discharges. Dam up. Soak with inert absorbent material. Pickup and transfer to properly labeled containers.

## Section 7. Handling and Storage

**Handling** Handle in accordance with good industrial hygiene and safety practice. Avoid contact with eyes and clothing. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing before re-use. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment.

**Storage:** Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep in properly labeled containers. Do not store near combustible materials. Keep in area equipped with sprinklers. Store in accordance with the particular national regulations. Store in accordance with local regulations.

**Incompatible materials:** None known based on information supplied.

## Section 8. Exposure Controls/Personal Protection

**Personal Protective Equipment** Goggles, Gloves

**Exposure guidelines:** There is no exposure data pertaining to the Product. This section reflects exposure data pertaining to individual ingredients.

**Other Exposure Guidelines:** national exposure control parameters.

**Engineering Controls:** Showers. Eyewash stations. Ventilation.

**Eye/Face Protection:** Tight sealing safety goggles.

**Skin and Body Protection:** Wear protective gloves/clothing. Long sleeved clothing. Impervious gloves.

**Respiratory Protection:** No protective equipment is needed under normal use conditions. If irritation is experienced, ventilation and evacuation may be required.

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety practice. Remove and wash contaminated clothing before re-use. Avoid contact with eyes and clothing.

## Section 9. Physical and Chemical Properties

|                                       |  |
|---------------------------------------|--|
| Physical State                        | Clear or Pink liquid                     |
| Color                                 | Pink, purple to slightly hazy, colorless |
| Odor                                  | Stream                                   |
| Odor Threshold                        | N/A                                      |
| Solubility                            | Soluble with water                       |
| Partition coefficient Water/n-octanol | N/A                                      |
| VOC%                                  | N/A                                      |

|                       |           |
|-----------------------|-----------|
| Viscosity             | N/A       |
| Specific Gravity      | 0.88      |
| Density lbs/Gal       | N/A       |
| Pounds per Cubic Foot | N/A       |
| Flash Point           | 23°C/73°F |
| FP Method             | N/A       |
| pH                    | 7.0       |

## Section 10. Stability and Reactivity

|                                     |  |
|-------------------------------------|--|
| Reactivity:                         | No data available.                           |
| Chemical stability:                 | Stable under recommended storage conditions. |
| Possibility of hazardous reactions: | None under normal processing.                |
| Hazardous polymerization:           | Does not occur.                              |
| Conditions to avoid:                | Heat. Open flame. Sparks.                    |

## Section 11. Toxicological Information

|                            |   |
|----------------------------|---|
| Likely Routes of Exposure: | Irritating to eyes. May cause redness, itching, and pain.   |
| Eye                        |   |
| Likely Routes of Exposure: | Prolonged contact may cause redness and irritation.   |
| Skin                       |   |
| Likely Routes of Exposure: | May cause irritation of respiratory tract.  |
| Inhalation                 |   |
| Likely Routes of Exposure: | Ingestion may cause irritation to mucous membranes. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. |
| Ingestion                  |   |
| Likely Routes of Exposure: | No information available.   |
| Component information:     |   |

## Section 12. Ecological Information

There is no ecological data on the Product. The Product ingredients are expected to be safe for the environment at concentrations predicted under normal use and accidental spill scenarios. Packaging components are compatible with the conventional solid waste management practices.

|                            |                           |
|----------------------------|---------------------------|
| Ecotoxicity:               | No information available. |
| Persistence/degradability: | No information available. |
| Bioaccumulation:           | No information available. |
| Other adverse effects:     | No information available. |



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## Section 13. Storage and Disposal

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**Waste Disposal Methods:** This material, as supplied, is not a hazardous waste  
This material could become a hazardous waste if it is mixed with or  
otherwise comes in contact with a hazardous waste.  
\*\*\*Dispose as per the local state regulations.

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## Section 14. Transport Information

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UN Proper Shipping Name CONSUMER COMMODITY  
DOT Classification 9  
Packing Group N/A  
IATA - UN Number: 1170  
IATA - UN Proper Shipping Name: CHG  
IATA - Hazard Class:  
IATA - Packing Group:

### Other information

The information presented herein is true and accurate to the best of our knowledge, but without guarantee unless explicitly given. Since the conditions of use are beyond our control, we disclaim any liability including for patent infringement incurred in connection with the use of these products, data or suggestions.

## 1 NAME OF THE MEDICINAL PRODUCT

Virox STERIZOL Sachets with Chlorhexidine 0.05 % w/v Antiseptic Cutaneous Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Gluconate 0.05 % w/v

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Antiseptic Cutaneous solution  
A clear, pink, solution.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

A broad spectrum antiseptic with detergent properties for swabbing in obstetrics and during dressing changes, disinfecting and cleansing traumatic and surgical wounds and burns.

### 4.2 Posology and method of administration

For topical application.

Cleanse affected area or involved skin with undiluted preparation.

### 4.3 Contraindications

1. Known hypersensitivity to the product or any of its components, especially in those with a history of possible chlorhexidine-related allergic reactions (see sections 4.4 and 4.8).
2. Use in contact with brain, meninges or middle ear.

### 4.4 Special warnings and precautions for use(Professional Medical USE Product)

Virox STERIZOL Sachets contains chlorhexidine. Chlorhexidine is known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock. The prevalence of chlorhexidine hypersensitivity is not known, but available literature suggests this is likely to be very rare. Virox STERIZOL Sachets should not be administered to anyone with a potential history of an allergic reaction to a chlorhexidine-containing compound (see sections 4.3 and 4.8).

The use of chlorhexidine solutions, both alcohol based and aqueous, for skin antiseptics prior to invasive procedures has been associated with chemical burns in neonates. Based on available case reports and the published literature, this risk appears to be higher in preterm infants, especially those born before 32 weeks of gestation and within the first 2 weeks of life.

Remove any soaked materials, drapes or gowns before proceeding with the intervention. Do not use excessive quantities and do not allow the solution to pool in skin folds or under the patient or drip on sheets or other material in direct contact with the patient. Where occlusive dressings are to be applied to areas previously exposed to Virox STERIZOL Sachets, care must be taken to ensure no excess product is present prior to application of the dressing.

1. When used in aseptic procedures, the outside of the sachet should be disinfected before opening.
2. Any surplus should be discarded immediately after use.
3. For external use only. NOT for injection.
4. Do not use within body cavities.
5. Contact with the eyes should be avoided.

### 4.5 Interaction with other medicinal products and other forms of interactions

Hypochlorite bleaches may cause brown stains to develop in fabrics which have previously been in contact

### 4.6 Fertility, pregnancy and lactation

Although there are no adverse reports for this product in pregnant and lactating mothers, as with all medicines, care should be exercised when administering the product to pregnant or lactating women.

### 4.7 Effects on ability to drive and use machines

None known.

## 4.8 Undesirable effects

Very Common ( $\geq 1/10$ ); Common ( $\geq 1/100$ ,  $< 1/10$ ); Uncommon ( $\geq 1/1,000$ ,  $< 1/100$ ); Rare ( $\geq 1/10,000$ ,  $< 1/1,000$ ); Very rare ( $< 1/10,000$ ); not known (cannot be estimated from the available data).

Skin and subcutaneous tissue disorders:

Frequency not known: Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters.

Immune system disorders:

Frequency not known: Hypersensitivity including anaphylactic shock (see sections 4.3 and 4.4).

Injury, poisoning and procedural complications:

Frequency not known: Chemical burns in neonates

## 4.9 Overdose

Accidental ingestion: Gastric lavage should be carried out with milk, egg white, gelatine or mild soap.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antiseptics and disinfectants,

Chlorhexidine is a disinfectant which is effective against a wide range of vegetative gram-positive and gram-negative bacteria; it is more effective against gram-positive than gram-negative bacteria, some species of *Pseudomonas* and *Proteus* being less susceptible. The wide range of organisms against which chlorhexidine is active explains the rationale for presenting it in a solution for swabbing wounds and burns and in obstetrics.

### 5.2 Pharmacokinetic properties

The BP 1993 contains monographs for Chlorhexidine Gluconate. The pharmacokinetics of the compounds when applied to the skin are well described in the literature.

### 5.3 Preclinical safety data

None stated.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Purified Water

Light pink

Sodium Hydroxide (for pH adjustment)

### 6.2 Incompatibilities

Virox STERIZOL Sachets with anionic agents

### 6.3 Shelf life

18 months.

Once opened use immediately and discard any unused portion.



## CERTIFICATE OF ANALYSIS

\*\*\*\*\*

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(EXTERNAL PREPARATIONS)

|  |                                       |
|--|---------------------------------------|
| <b>NAME OF PRODUCT : VIROX STERIZOL -CHLORHEXIDINE GLUCONATE 0.05w/v</b> |                                       |
| <b>BATCH NO. : 23Z82</b>   | <b>DATE OF RETEST : 11/06/2023</b>    |
| <b>MFD. : Jun. 2023 :</b>  | <b>QTY OF SAMPLE : 10 x 25 ml pac</b> |
| <b>EXP. Jun. 2025 :</b>  | <b>Q.C. REPORT NO k : FP/23/Z/82</b>  |
| <b>BATCH SIZE 10 Lit</b>   | <b>DATE OF PASSING : 08/07/2023</b>   |

### A] GENERAL TEST

| SR. NO | TEST PROTOCOL  | OBSERVATIONS  | RESULTS                           |
|--------|----------------|---|-----------------------------------|
| 1.     | Description    | Pink colour clear liquid filled in 25 ml Plastic pouch. | Passes.                           |
| 2.     | Identification | Complies  | Passes.                           |
| 3.     | PH             | 6.10  | Passes.                           |
| 4.     | Weight per ml  | 0.9945 g/ml   | 0.9920 g/ml<br>to 0.9980<br>gm/ml |

### B] ASSAY

| SR. NO. | INGREDIENTS                         | LABELLED CLAIM | ESTIMATED AMOUNT | % ESTIMATED AMOUNT | LIMITS                |
|---------|-------------------------------------|----------------|------------------|--------------------|-----------------------|
| 1.      | Chlorhexidine Gluconate Solution IP | 0.05%w/v       | 0.0498 %w/v      | 102.30 %           | 90.0%<br>To<br>110.0% |

### C] BACTERICIDAL EFFICACY TEST

| SR. NO. | PARAMETER                 | Observation            | Results       |
|---------|---------------------------|------------------------|---------------|
| 1.      | <b>Standard Method</b>    | <b>BS EN 1656:2019</b> | <b>Passes</b> |
| 2.      | Appearance of the product | Pink colour liquid     | Passes        |
| 3.      | Storage Condition         | Ambient                | Passes        |

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|     |   |   |        |
|-----|---|---|--------|
| 4.  | Preservative                                | Sodium Benzoate   | Passes |
| 5.  | Product Diluents                            | Distilled water<br>Freshly boiled & cooled                                  | Passes |
| 6.  | Test Concentration                          | Less than 80 %  | Passes |
| 7.  | Experimental condition                      | Clean Room area with<br>RLAF  | Passes |
| 8.  | Interfering substance                       | 3 g/Lit Bovine albumin  | Passes |
| 9.  | Test Temperature                            | 20°C ± 1°C  | Passes |
| 10. | Temperature of Incubation                   | Bacteria – 37°C ±1°C for<br>2 Days  | Passes |
| 11. | Identification of the<br>Bacterial strains: | Pseudomonas aeruginosa NCTC<br>13359<br>Staphylococcus aureus NCTC<br>10788 | Passes |
| 12. | Contact Time                                | 5 min ± 10 s ( Surface)   | Passes |
| 13. | Acceptance Criteria                         | 5 log10   | Passes |

**Conclusion.**

The product Germinil AL has passed the test according to the acceptance criteria as outlined in the standard for general disinfection, when tested under clean conditions with a contact time of **5 minutes** at a minimum concentration of 50%.

**OPINION** :In the opinion of the undersigned sample referred to above is of standard quality / ~~not of standard quality~~ as defined in the act and rules there under for the reason given below.

Above performed tests complies **as per Labelled** Specification with respect to customer requirement.

ANALYST

Q.C. INCHARGE

Remark :The sample will be retained for 1 month unless otherwise requested.