STERISEPT

Virox STERISEPT Antiseptic solution for disinfecting and cleansing traumatic and surgical wounds and burns. STERISEPT Sachets is a broad-spectrum antiseptic with detergent properties 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 STERISEPT Sachet contains 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 It also contains Cetrimide, a disinfectant with bactericidal properties that helps to cleanse the skin and wound.

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

Provides antimicrobial protection against a wide range of common organisms
Helps to support hospital infection control protocols
solution that supports the aseptic process
Yellow coloured for easy identification and to avoid misuse

25 ml aqueous solution containis
chlorhexidine gluconate 0.05% w/v and centermide 0.15% w/v .

SCCGC0025 Pack of 20 sachets

Swiss Chemi Pvt. Ltd
Saras3/2, Kalash Udyan, Sec- 11, Koperkhairne, Navi Mumbai - 400709 INDIA
info@swisschemi.com

Safety Data Sheet

VIROX STERISEPT

Section 1. Identification

Product Identifier	**VIROX-STERISEPT**
Manufacturer Stock Numbers	SCCGC******,
Recommended use	Skin Disinfection
Contact Address	Swiss chemi Pvt Ltd Navi Mumbai INDIA - 400709

Phone
+91 9359530990

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+91 9359530990

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www.swisschemi.com

Section 2. Hazards Identification

Classification	NON FLAMMABLE LIQUIDS -
Signal Word	
Pictogram	

Section 3. Ingredients

CAS	Ingredient Name	Weight %
1119-97-7	Cetrimide	0.15%
18472-51-0	Chlorhexidine gluconate	< 0.05%
7732-18-5	Water	

Section 4. First-Aid Measures

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

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CERTIFICATE OF ANALYSIS

****

(EXTERNAL PREPARATIONS)

NAME OF PRODUCT : VIROX STERISEPT - CHLORHEXIDINE GLUCONATE 0.05% WVAND CENTERMIDE 0.15% W/V	
BATCH NO. : 23A40	**DATE OF RETEST : 04/04/2023**
MFD. : JAN. 2023	**QTY OF SAMPLE : 10 x 25 ml pack**
EXP. : DEC. 2024	**Q.C. REPORT NO : FP/23/A/40**
BATCH SIZE : 10 Lit	**DATE OF PASSING : 13/04/2023**

A] GENERAL TEST

SR. NO	TEST PROTOCOL	OBSERVATIONS	RESULTS
1.	Description	Orange 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 to 0.9980 gm/ml

B] ASSAY

SR. NO.	INGREDIENTS	LABELLED CLAIM	ESTIMATED AMOUNT	% ESTIMATED AMOUNT	LIMITS
1.	Cetrimide IP	0.15%w/v	0.1485 % w/v	101.42 %	90.0% To 110.0%
2.	Chlorhexidine Gluconate Solution IP	0.05%w/v	0.0498 %w/v	102.30 %	

C] BACTERICIDAL EFFICACY TEST

SR. NO.	PARMETER	Observation	Results
1.	**Standard Method**	**BS EN 1656:2019**	**Passes**
2.	Appearance of the product	Orange colour liquid	Passes
3.	Storage Condition	Ambient	Passes

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4.	Preservative	Sodium Benzoate	Passes
5.	Product Diluents	Distilled water Freshly boiled & cooled	Passes
6.	Test Concentration	Less than 80 %	Passes
7.	Experimental condition	Clean Room area with 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 2 Days	Passes
11.	Identification of the Bacterial strains:	Pseudomonas aeruginosa NCTC 13359 Staphylococcus aureus NCTC 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.

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 (CO2). 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 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 of 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 yellow liquid
Color	Yellow to slightly hazy, colorless
Odor	Stream
Odor Threshold	N/A
Solubility	Miscible 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: Eye	Irritating to eyes. May cause redness, itching, and pain.
Likely Routes of Exposure: Skin	Prolonged contact may cause redness and irritation.
Likely Routes of Exposure: Inhalation	May cause irritation of respiratory tract.
Likely Routes of Exposure: Ingestion	Ingestion may cause irritation to mucous membranes. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.
Likely Routes of Exposure: Component information:	No information available.

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.

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Virox STERISEPT Sachets Centermide 0.15% w/v and Chlorhexidine 0.05 % w/v Antiseptic Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Gluconate 0.05 % w/v
Cetrimide 0.15 % w/v

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Antiseptic Cutaneous solution
A clear, yellow, solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A broad spectrum antiseptic with detergent properties for swabbing in obstetrics and for 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

Virox STERISEPT 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 STERISEPT 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 antisepsis 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 STERISEPT 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.

Section 13. Storage and Disposal

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.

Section 14. Transport Information

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.

4.8 Undesirable effects

Very Common (≥ 1/10); Common (≥ 1/100, < 1/10); Uncommon (≥ 1/1,000, < 1/100); Rare (≥ 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

In addition, cetrimide has been reported to cause dry skin and in rare cases chemical burn after repeated application.

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.
Cetrimide is a quaternary ammonium disinfectant with properties and uses typical of cationic surfactants. It is used in Sterets Tisept Sachets antiseptic for its surfactant and bactericidal properties.

5.2 Pharmacokinetic properties

The BP 1993 contains monographs for both Chlorhexidine Gluconate and Cetrimide. 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
Sunset Yellow (E110)
Sodium Hydroxide (for pH adjustment)

6.2 Incompatibilities

Virox STERISEPT Sachets with anionic agents

6.3 Shelf life

18 months.
Once opened use immediately and discard any unused portion.