

STERITE PLUS- benzalkonium chloride liquid
PALVI MEXICO, S.A. DE C.V.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

STERITE PLUS SANITIZER

ACTIVE INGREDIENTS

DIDECYLDIMONIUM CHLORIDE

BENZALKONIUM CHLORIDE

OTC PURPOSE SECTION

PURPOSE

ANTIMICROBIAL

INDICATIONS AND USAGE

HAND AND SURFACE DISINFECTANT TO HELP REDUCE BACTERIA THAT POTENTIALLY CAUSE DISEASES

DOSAGE AND ADMINISTRATION

DIRECTIONS SPRAY STERITE NEUTRUM ON 12 TO 16 INCHES OVER HANDS, RUB AND AIR DRY, ON SURFACES APPLYING A FINE MIST, WIPE CLEAN. NO RINSING REQUIRED.

WARNINGS AND PRECAUTIONS SECTION

DO NOT USE ON OPEN WOUNDS ON THE SKIN, EYES OR MUCOUS MEMBRANES

DO NOT USE IN EYES. IF CONTACT OCCURS, FLUSH THE EYES WELL WITH PLENTY OF WATER.

WARNINGS

WARNING FOR EXTERNAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

KEEP OUT OF REACH OF CHILDREN

INACTIVE INGREDIENT SECTION

INACTIVE INGREDIENTS: WATER, N-NONYLPHENOL, EUCALYPTOL, LEMON OIL, DISODIUM EDTA, FD&C GREEN NO.3

PACKAGE LABEL SECTION

Sterite Plus is a disinfectant formulated with quaternary ammonium, with residual action which is effective against viruses, bacteria and fungi.

The pleasant lemon-lime fragrance of **Sterite Plus** helps provide a more comfortable environment for patients, clients, staff and the general public.

For use on hands, inanimate, porous and non-porous surfaces, in hospitals, doctor's offices and clinical laboratories, dentists, nursing homes, veterinary clinics, clubs, spas, restaurants, hotels, schools, at home, etc.



INDUSTRIA MEXICANA
Manufactured by Palvi México S.A de C.V.
Casuarina 1388, Zapopan 45069 Jal.
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READ THE LABEL BEFORE USING THIS PRODUCT. DO NOT REUSE THE CONTAINER, ONE THE CONTENTS ARE FINISHED, DISPOSE OF THE CONTAINER



Sterite[®]
PLUS

HAND AND SURFACE SANITIZER

FOR ALL TYPES OF SURFACE
READY TO USE

ELIMINATES VIRUSES, BACTERIA AND FUNGI



LEMON ESSENCE



DRUG FACTS

ACTIVE INGREDIENT & PURPOSE

Didecyldimonium chloride 0.18%.....Antimicrobial
Benzalkonium chloride 0.06%.....Antimicrobial

USES:

Hand and Surface disinfectant to help reduce bacteria that

WARNING: For external use only. "Do not use ON open wounds on the skin, eyes or mucous membranes.

DO NOT USE IN EYES. If contact occurs, flush the eyes well with plenty of water

KEEP OUT OF REACH OF CHILDREN: Stop use and see a doctor if irritation or rash occurs. These could be signs of a serious condition.

DIRECTIONS: Spray **Sterite Plus** on 12 to 16 inches over hands, rub and air dry, on surfaces applying a fine mist, wipe clean. No rinsing required.

INACTIVE INGREDIENTS: WATER, N-NONYLPHENOL, LEMON OIL, DISODIUM EDTA, FD&C GREEN No 3.

STERITE PLUS

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81576-1000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZ ALKONIUM CHLORIDE	0.0006 mg in 1 mL
DIDECYLDIMONIUM CHLORIDE (UNII: JXN40O9Y9B) (DIDECYLDIMONIUM - UNII:Z7F472XQPA)	DIDECYLDIMONIUM CHLORIDE	0.0018 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	0.0003 mL in 1 mL

N-NONYLPHENOL (MIXED ISOMERS) (UNII: 79F6A2ILP5)	0.007 mL in 1 mL
WATER (UNII: 059QF0KO0R)	0.99 mL in 1 mL
LEMON OIL (UNII: I9GRO824LL)	0.0002 mL in 1 mL
ACID GREEN 50 (UNII: 9B7E8Y9D0X)	0.0001 mL in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81576-1000-2	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/16/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/16/2021	

Labeler - PALVI MEXICO, S.A. DE C.V. (824338511)

Registrant - PALVI MEXICO, S.A. DE C.V. (824338511)

Establishment

Name	Address	ID/FEI	Business Operations
PALVI MEXICO, S.A. DE C.V.		824338511	manufacture(81576-1000)

Revised: 2/2021

PALVI MEXICO, S.A. DE C.V.