SANIVIR HANDS, BODY, AND SURFACES SANITIZER- didecyldimonium chloride and benzalkonium chloride liquid liquid SANIVIR GEL PLUS HAND SANITIZER- didecyldimonium chloride and benzalkonium chloride liquid gel Kemix Quimica, 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.

SANIVIR Sanitizer

SANIVIR Certificate of Analysis



LABORATORIO DE ANALISIS DE CALIDAD Batab Health Care SA de CV

CERTIFICADO DE ANALISIS

Mérida Yucatán 01/09/2020

Producto:

SANIVIR SANITIZANTE VIRUCIDA

Clave:

SVA

Fórmula:

SVA SANIVIR SANITIZANTE VIRUCIDA KEMIX

Fecha de fabricación:

19/08/2020

Lote:

20/283

Fecha de caducidad:

08/2024

Marca:

KEMIX

Resultados de pruebas:

FISICOQUIMICAS

COMPONENTES ANALIZADOS	% CONCENTRACION MEDIDA	TIPO ANALISIS QUIMICO
AGUA PURIFICADA	88.63	CUANTITATIVO
ALCOHOL ETILICO	8	CUANTITATIVO
ALCOHOL ISOPROPILICO	2	CUANTITATIVO
GLICERINA	0.5	CUANTITATIVO
DIDECYL DIMETHYL AMMONIUM CHLORIDE	0.25	CUANTITATIVO
BENZALKONIUM CHLORIDE	0.1	CUANTITATIVO
TRIETANOLAMINA	0.02	CUANTITATIVO

Certificamos que el análisis fisicoquímico de lote de producto, solicitado por **Kemix Química SA de CV**, contiene las especificaciones arriba mencionadas.

ATENTAMENTE

DATAB HEALTH CARE S.A. DE C.V

Q.F.B. Cristina Balam Euan Laboratorio de Analisis de Calidad

Batab Health Care SA de CV BHC 0502257N9 www.mayasolar.mx



LABORATORIO DE ANALISIS DE CALIDAD Batab Health Care SA de CV

CERTIFICADO DE ANALISIS

Mérida Yucatán 29/10/2020

Producto:

SANIVIR GEL PLUS SANITIZANTE VIRUCIDA

Clave:

SVG

Fórmula:

SVG SANIVIR GEL PLUS KEMIX

Fecha de fabricación:

12/10/2020

Lote:

10/352

Fecha de caducidad:

10/2024

Marca:

KEMIX

Resultados de pruebas:

FISICOQUIMICAS

COMPONENTES ANALIZADOS	% CONCENTRACION MEDIDA	TIPO ANALISIS QUIMICO
AGUA PURIFICADA	29.13	CUANTITATIVO
ALCOHOL ETILICO	70	CUANTITATIVO
GLICERINA	0.5	CUANTITATIVO
ACIDO POLIACRILICO	0.35	CUANTITATIVO
TRIETANOLAMINA	0.02	CUANTITATIVO

Certificamos que el análisis fisicoquímico de lote de producto, solicitado por **Kemix Química SA de CV**, contiene las especificaciones arriba mencionadas.

ATENTAMENTE

BATAB HEALTH CARE S.A. DE C.Y.

Q.F.B. Cristina Balam Euan Laboratorio de Analisis de Calidad

Batab Health Care SA de CV BHC 0502257N9 www.mayasolar.mx



STORAGE AND TRANSPORTATION: Keep in a dry and cool place, in its well covered container. ACTIVE INGREDIENTS: Didecyl Dimethyl Ammonium Chloride and Benzalkonium Chloride.

OTHER INGREDIENTS: Water, Alcohols, Glycerin, Magnesium Disodium EDTA.



FDA Labeler Code: 77396 Manufactured by: Kemix Química, S.A de C.V **NET CONTENT** 1000 Lt /219.97 GALLONS

♦ Color: Transparent Blue

♦ Oddor: Odorless ♦ Specific weight: 1.01 kg / lt

♦ Solubility: 100%

♦ Presentation: Liquid



Imported by:

Mérida, Yucatán

www.kemix.com.mx

■ Keep out of reach of children. Children must be supervised when using this product. Stop use and ask a doctor if redn velop and persist for more than 72 hours

Drug Facts

Active ingredients

Didecyl Dimethyl

Uses

Ammonium Chloride 0.25% Benzalkonium Chloride 0.1%

Warnings
For external use only
Avoid eye contact.
Do not ingest.

When using this product

 Hand Sanitizer helps to reduce bacteria and viruses on the skin and surfaces when water, soap and towel are not aviable.

Recommended for repeated use.

Purpose

Directions Hands and body: Apply a generous amount

In case of eye contact, remove contact lense and immediately flush withrunning water for at least 15 minutes, holding eyelids open.

If swallowed: Induce vomiting.

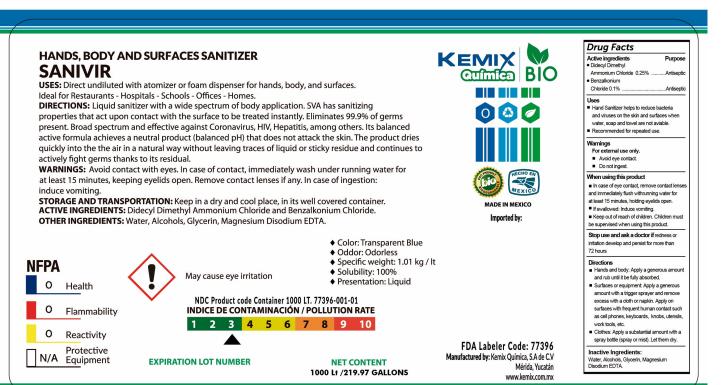
- and rub until it be fully absorbed.

 Surfaces or equipment: Apply a generou amount with a trigger sprayer and remove excess with a cloth or napkin. Apply on surfaces with frequent human contact such
- Clothes: Apply a substantial amount with a spray bottle (spray or mist). Let them dry.

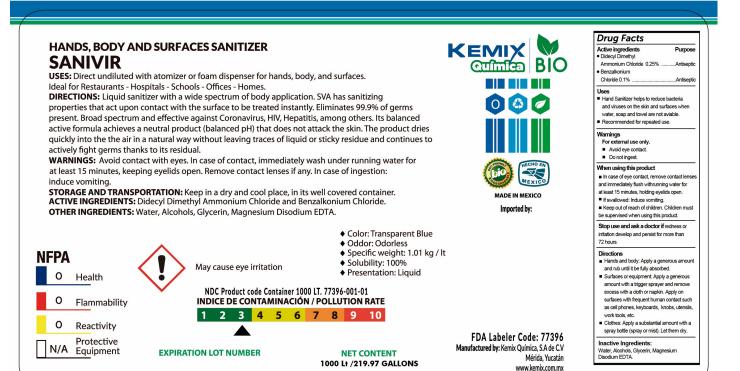
Inactive Ingredients: Water, Alcohols, Glycerin, Magnesium Disodium EDTA.

DOSAGE AND ADMINISTRATION SECTION

WARNINGS

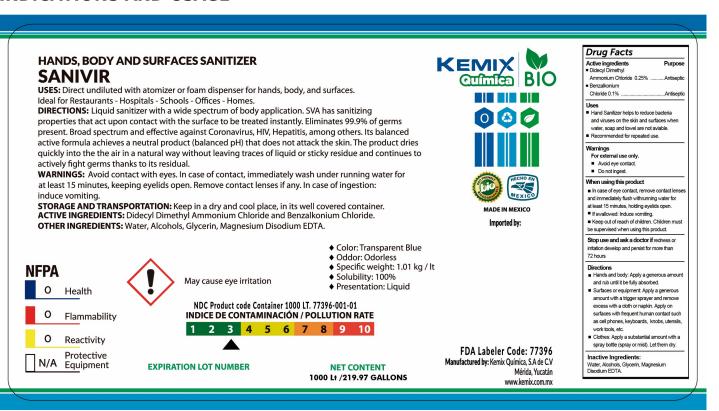


WARNINGS



INACTIVE INGREDIENTS

INDICATIONS AND USAGE



INDICATIONS AND USAGE SECTION



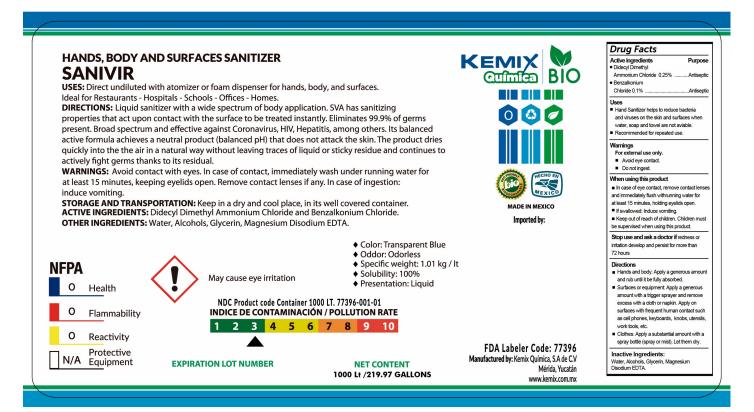
KEEP OUT OF REACH OF CHILDREN SECTION

PURPOSE



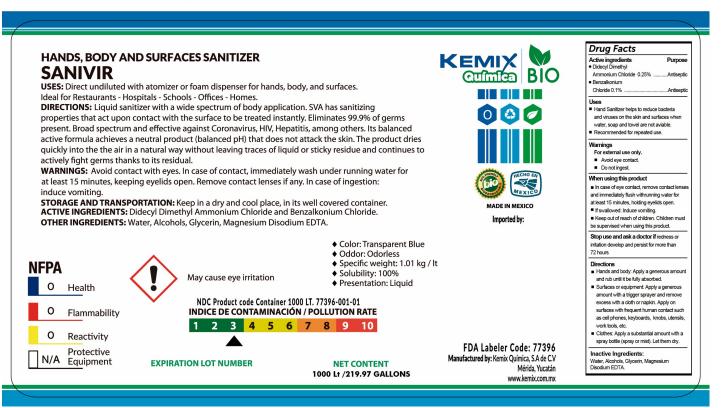
OTC - PURPOSE SECTION

ACTIVE INGREDIENT

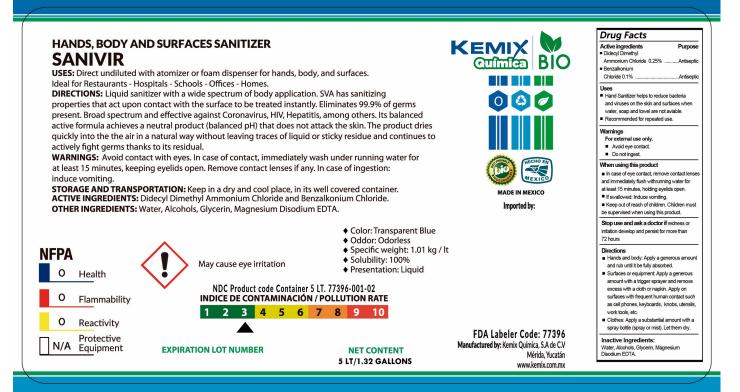


ACTIVE INGREDIENT

SANIVIR Hands, Body, and Surfaces Sanitizer 1,000 Lt (264 gallons)



77396-001-01



77396-001-02

SANIVIR Hands, Body, and Surfaces Sanitizer 75ml (2.4fl.oz)



NDC: 77396-01-003

SANIVIR Gel Plus Sanitizer 75ml (2.4fl.oz)



NDC: 77396-002-02

SANIVIR Gel Plus Sanitizer 5Lt (1.32gal)

HAND SANITIZER SANIVIR GEL PLUS

USES: Hand and body sanitizer with Alcohol and 5G Quaternary Ammonium Compounds eliminating bacteria and viruses on skin.

DIRECTIONS: Hands and body, Apply a generous amount and rub until it be fully absorbed.

WARNINGS: For external use only Flammable keep away from heat and flame.

When using this product keep out of eyes. In case of contact with eyes flush thoroughly with water for at least 15 minutes keeping eyelids open.

Avoid contact with skin wounds.

If swallowed do not induce vomiting. Get medical help or contact a Poison Control Center immediately. Keep out of children reach.

STORAGE AND TRANSPORTATION: No special ventilation is required. Store closed in a clean, shaded, and dry place

May cause eye irritation

ACTIVE INGREDIENTS: Didecyl Dimethyl Ammonium Chloride and Benzalkonium Chloride.

OTHER INGREDIENTS: Water, Alcohols, Polyacrylate, Glycerin, Triethanolamine.



Imported by:

MADE IN MEXICO

- ◆ Color: Transparent Blue
- ♦ Oddor: Alcohol
- ♦ Specific weight: 0.974 kg/lt
- ♦ Solubility: 100%
- ♦ Presentation: Gel



EXPIRATION LOT NUMBER

NET CONTENT 5 LIT/1.32 GALLONS

FDA Labeler Code 77396 Manufactured by: Kemix Química, S.A de C.V. Mérida, Yucatán www.kemix.com.mx



Warnings For external use only.

- Avoid eye contact.
- Do not ingest.
- Avoid contact with skin wounds

When using this product

- In case of eye contact, remo and immediately flush withrunning water for at least 15 minutes, holding eyelids open.
- If swallowed: Do not Induce vomiting., get medical help or contact a Poison Control Center immediately
- Keep out of reach of children. Children must be supervised when using this product.

Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours

Directions

■ Hands: Apply a generous amount

Inactive Ingredients: Water, Alcohols, Polyacrylate, Glycerin, Triethanolamine

NDC: 77396-002-01

Flammability

Reactivity

N/A Protective Equipment

NFPA

SANIVIR HANDS, BODY, AND SURFACES SANITIZER

didecyldimonium chloride and benzalkonium chloride liquid liquid

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:77396-001 **Route of Administration TOPICAL**

Active Ingredient/Active Moiety			
Ingredient Name Basis of Strength			
DIDECYLDIMONIUM CHLORIDE (UNII: JXN4009Y9B) (DIDECYLDIMONIUM - UNII: Z7F472XQPA)	DIDECYLDIMONIUM CHLORIDE	2.5 mg in 0.001 L	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1 mg in 0.001 L	

Inactive Ingredients				
Ingredient Name	Strength			
TRIETHANOLAMINE TRIS(DIHYDROGEN PHOSPHATE) (UNII: 36YHT392ID)				
ALCOHOL (UNII: 3K9958V90M)				
WATER (UNII: 059QF0KO0R)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
GLYCERIN (UNII: PDC6A3C0OX)				

P	Packaging				
# Item Code Package Description		Marketing Start Date	Marketing End Date		
1	NDC:77396- 001-01	1000 L in 1 CONTAINER; Type 0: Not a Combination Product	12/12/2020		
2	NDC:77396- 001-02	5 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/12/2020		
3	NDC:77396- 001-03	0.075 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/12/2020		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/07/2020	

SANIVIR GEL PLUS HAND SANITIZER

didecyldimonium chloride and benzalkonium chloride liquid gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77396-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name Basis of Strength			
DIDECYLDIMONIUM CHLORIDE (UNII: JXN4009Y9B) (DIDECYLDIMONIUM - UNII: Z7F472XQPA)	DIDECYLDIMONIUM CHLORIDE	2.5 mg in 0.001 L	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1 mg in 0.001 L	

Inactive Ingredients			
Ingredient Name	Strength		
TROLAMINE (UNII: 903K93S3TK)			
ALCOHOL (UNII: 3K9958V90M)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
WATER (UNII: 059QF0KO0R)			
MAGNESIUM DISODIUM EDTA (UNII: NDT563S5VZ)			
METHYL ALCOHOL (UNII: Y4S76JW15)			
GLYCERIN (UNII: PDC6A3C0OX)			

F	Packaging			
#	# Item Code Package Description		Marketing Start Date	Marketing End Date
1	NDC:77396-	0.075 L in 1 BOTTLE, PLASTIC; Type 0: Not a	05/12/2020	

002-02	Combination Product	U3/13/2U2U	ĺ
NDC:77396- 002-01	5 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/13/2020	

Marketing Information			
Marketing End Date			

Labeler - Kemix Quimica, S.A. de C.V. (813182128)

Registrant - VR International LLC (074181935)

Establishment			
Name	Address	ID/FEI	Business Operations
Kemix Quimica, S.A. de C.V.		813182128	manufacture(77396-001, 77396-002)

Revised: 1/2022 Kemix Quimica, S.A. de C.V.