

ART NATURALS- hand sanitizing wipes, ethanol cloth
SEPA MENSUCAT SANAYI VE TICARET ANONIM SIRKETI

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.

HAND SANITIZING WIPES

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Ethanol 75% Purpose: Antiseptic

Purpose

Antiseptic

Use

Single use wipes to reduce bacteria that potentially can cause disease. For use when soap and water are not available

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

These wipes do not replace wipes used for medical procedures

If eye contact occurs flush eyes with water

Stop use if irritation and redness develop. If condition continues, consult your health care practitioner

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Unfold towelette, wipe hands, discard after use

Other information

- Store at room Temperature 59-86F

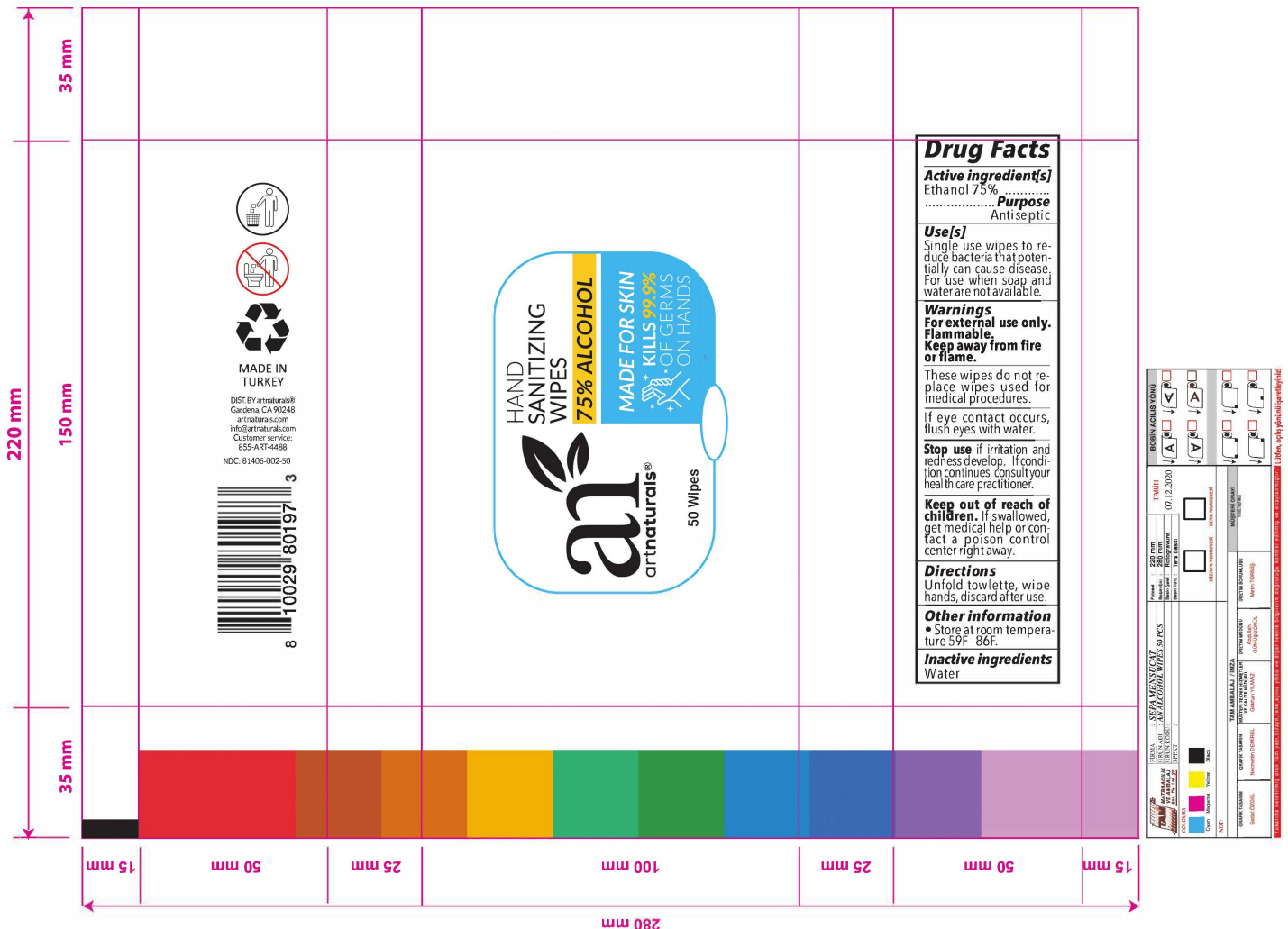
Inactive ingredients

Water

Package Label - Principal Display Panel

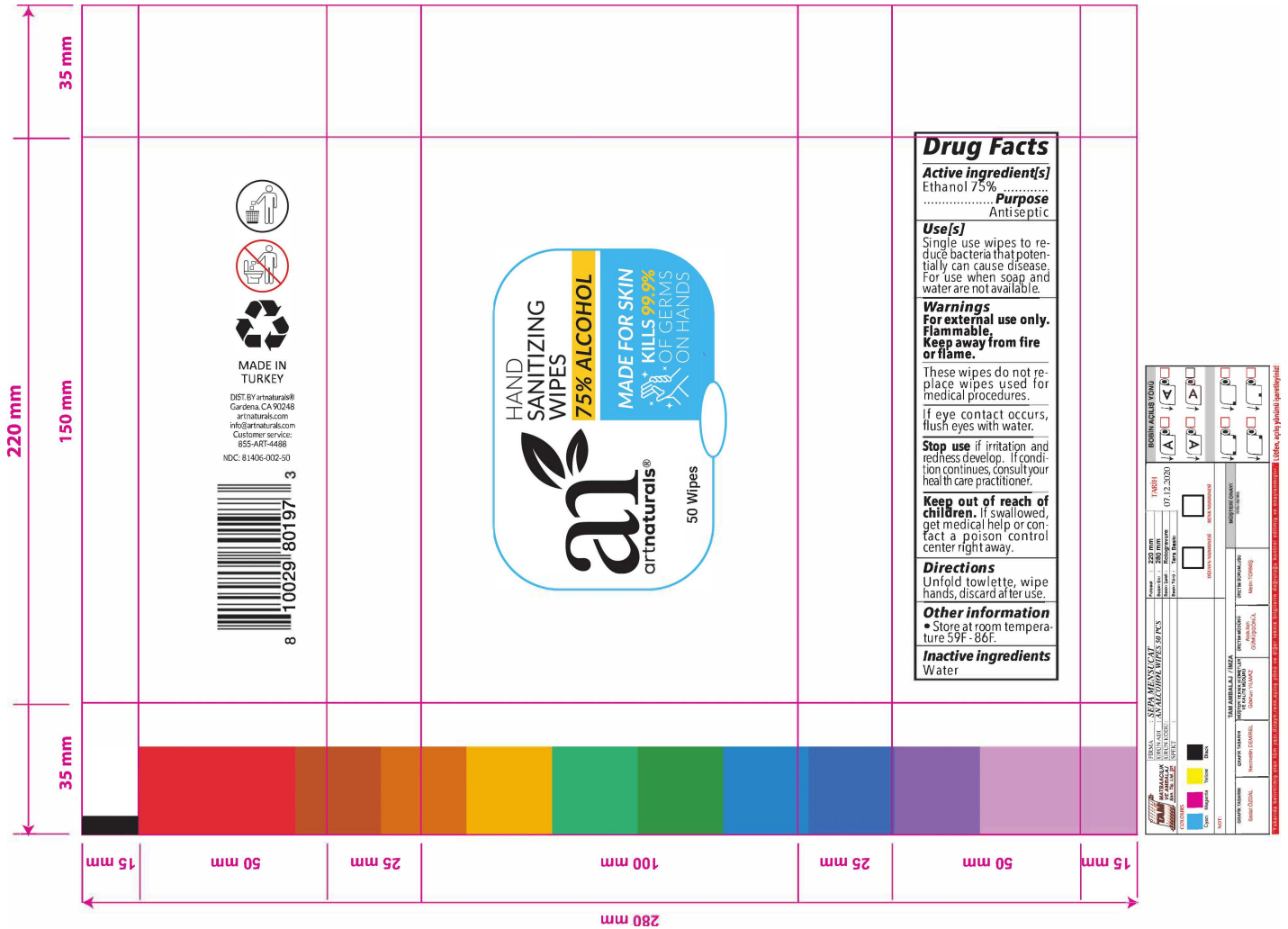
50 pcs

200 gr NDC: 81406-002-50



Hand Sanitizing Wipes- 50 pcs
NDC: 81406-002-50

Hand Sanitizing Wipes- 50 pcs-200 gr
 NDC: 81406-002-50



ART NATURALS			
hand sanitizing wipes, ethanol cloth			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81406-002
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 g in 100 g	
Inactive Ingredients			

Ingredient Name		Strength		
WATER (UNII: 059QF0KO0R)		25 g in 100 g		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81406-002-50	200 g in 1 POUCH; Type 0: Not a Combination Product	02/15/2021	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	02/15/2021		

Labeler - SEPA MENSUCAT SANAYI VE TICARET ANONIM SIRKETI (366438166)

Registrant - SEPA MENSUCAT SANAYI VE TICARET ANONIM SIRKETI (366438166)

Establishment

Name	Address	ID/FEI	Business Operations
SEPA MENSUCAT SANAYI VE TICARET ANONIM SIRKETI		366438166	manufacture(81406-002)

Revised: 10/2021

SEPA MENSUCAT SANAYI VE TICARET ANONIM SIRKETI