SANIPOWER HAND SANITIZER- hand sanitizer gel
IVERO d.o.o.

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.

Active Ingredients

Isopropyl Alcohol 15%

Ethyl Alcohol 55%

Benzalkonium chloride 0.0165%

Purpose

Antiseptic

Use

To reduce harmful bacteria on skin.

Directions For Use

- Apply 3-5mL (approx. 1 tsp) of product to dry hands and wrists and rub until dry (at least 30 seconds). Period required for biocidal effect: 30-60 seconds.
- For external use only.
- Supervise children under 6 years of age when using product to avoid swallowing.

Hazard Statements

- Causes serious eye irritation. Highly flammable liquid and vapor. May cause drowsiness or dizziness.

Precautionary Statements

- Keep out of reach of children.
- Do not use on children less than 2 months of age.
- Do not use on open skin wounds.
- If in eyes, rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do; continue rinsing. If eye irritation persists, get medical advice/attention.
- Avoid breathing dust/fumes/gas/mist/vapors/aerosol.
- Keep away from heat, hot areas, sparks, open flames and other sources of ignition such as smoking.
- Store in a well-ventilated place between 15-30°C (59-86°F). Keep container tightly closed. Dispose of contents/container in accordance with national regulations.

Keep out of reach of children.

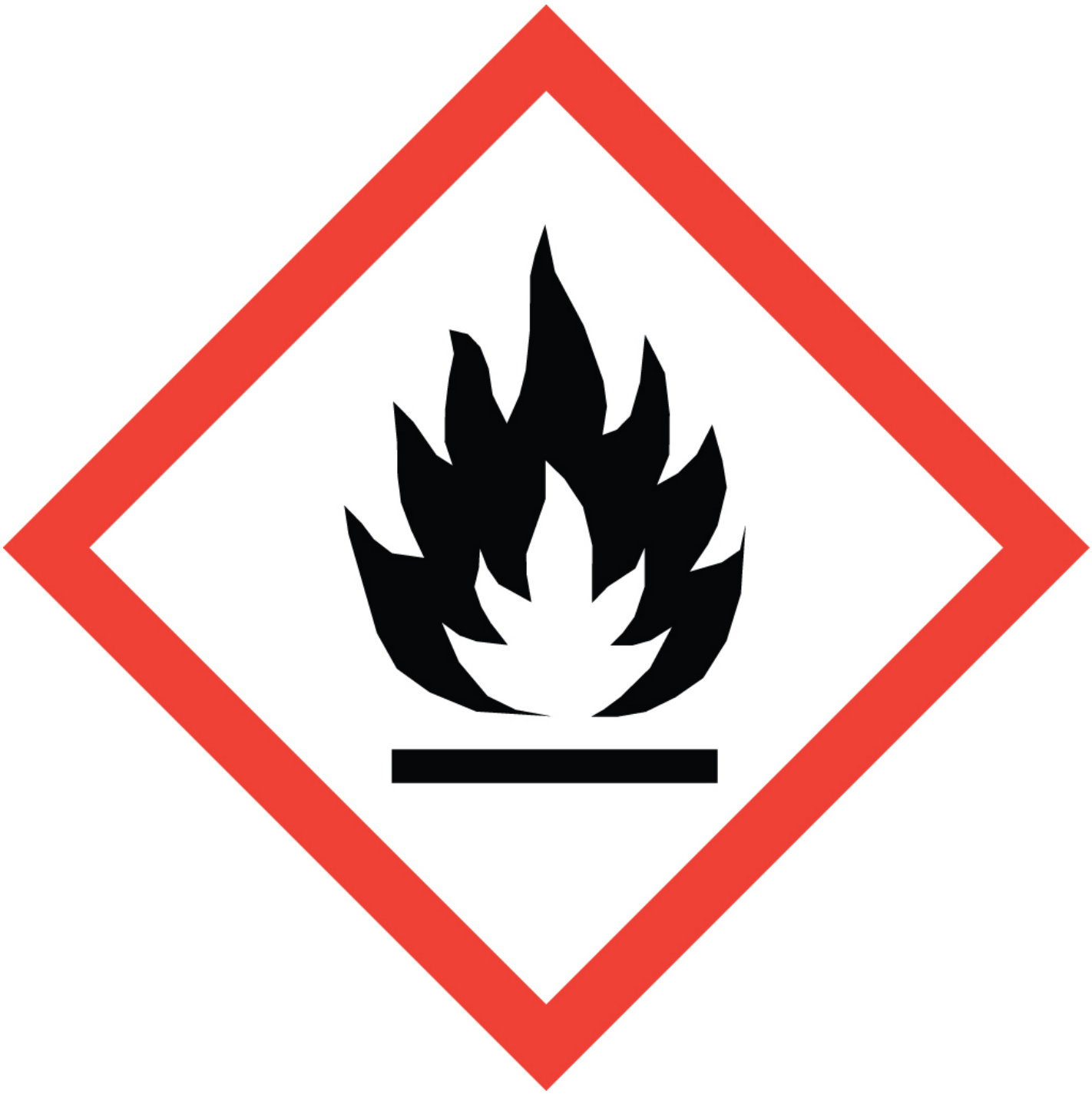
Note

Read accompanying leaflet before use. Call Poison Control if you feel unwell after use - (800) 222-1222. **For additional information, see safety data sheet.**

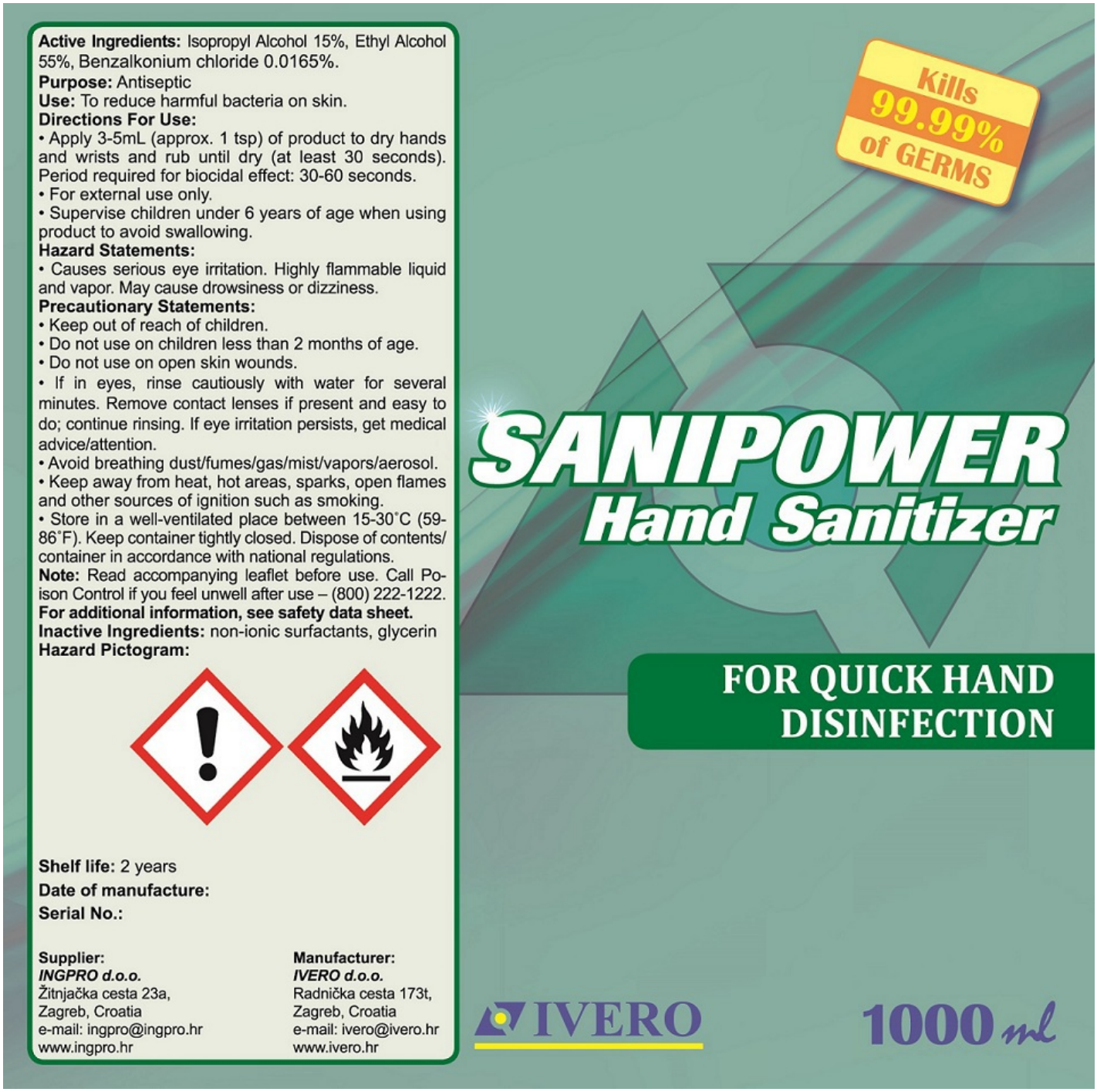
Inactive Ingredients

non-ionic surfactants, glycerin

Hazard Pictogram



Package Label - Principal Display Panel



1000mL NDC: 80133-003-10

SANIPOWER HAND SANITIZER

hand sanitizer gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80133-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	55 mL in 100 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	15 mL in 100 mL
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.0165 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80133-003-10	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/09/2020	

Labeler - IVERO d.o.o. (499600898)

Revised: 9/2020 IVERO d.o.o.