

湖北鸿瑞塑料有限公司
HUBEI HONGRUI PLASTICS CO., LTD.
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No. TCF192331-3

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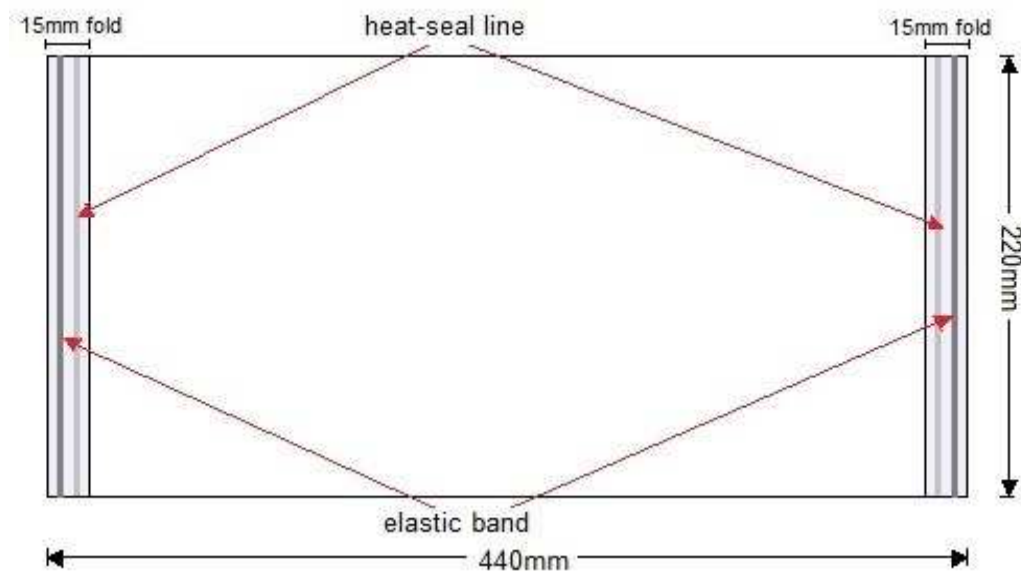
Product Data Sheet

Customer : Norengros AS, Fyrstikkalléen 3A, 0661 Oslo, Norway

Product Description

Product : Polythene Sleeve Covers (Art. no. 192331)
Colour : White
Material : 95% LDPE, 5% white masterbatch **food-grade
Thickness : 20 micron, smooth surface
Weight : net 3.4 grams (+/-5%)
Size : Length 440 mm (+/- 3%) Width: 220 mm (+/- 3%)
Natural opening of cuff: 65mm (+/-5%)
Stretch opening of cuff: 220 mm (+/-3%)

Elastic band : 1 mm x 110 mm (latex free)



Packing : 10 pcs. per bundle, 10 bundles per polybag, 2000 pcs. per export carton
Carton meas. : 37 x 27 x 36 cm
G.W./N.W. : 7.3 kgs / 7.0 kgs

Suggested Sterilization

ETO: (pre-treatment cycle 16-72 hrs)
(gas contact – 3 hrs/850 mg)
(evaporation 48 hrs at 40°C)

Suggested Storage:

Temperature : between -5°C and 40°C

Humidity : below 80%

Sunlight : not to expose to direct sunlight

Shelf-Life : 3 years

Intended Use: It is in liquid repellent polyethylene plastic to protect sleeves from splashes or smearing. It can be used in cooking, cleaning, patient care, or workwear in food industry, or other industries.

Applicable Directive/Regulation:

Directive 93/42/EEC for medical device class I

Regulation (EU) 2016/425 for PPE cat. I

Regulation (EC) No: 1935/2004, 2023/2006. Regulation (EU) No: 10/2011, 1282/2011, 1183/2012, 202/2014.

Regulation (EU): 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831, 2019/37, 2019/1338, 2020/1245, 2023/1442, 2023/1627 & BfR Empf. IX for food contact.

Risk Analysis

The raw material is approved to be safe to human health (referring to the manufacturer's safety data sheet). As for the product, no hazard is foreseeable to the safety and health of user.

Cautions:

1. This product is for single use. Do not re-use it.
2. This product is for hygienic protection, not for any other personal protection against potential risk.
3. This product is non-sterile. It must be sterilized before being used as sterile wear.
4. It may cause skin at cuff part discomfort when wearing for a long time, especially for people who is with allergic skin.
5. Do not wear it in the place where electrostatic prevention is requested. It is not anti-static treated.