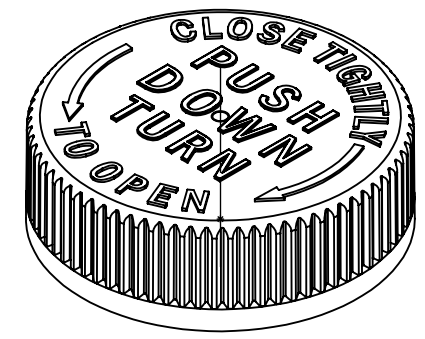
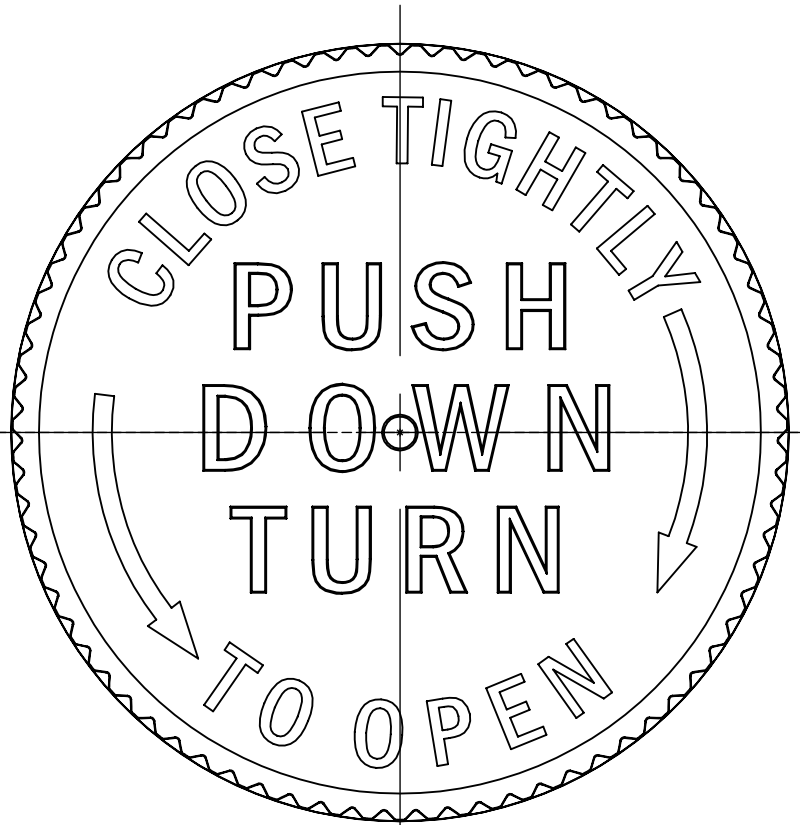
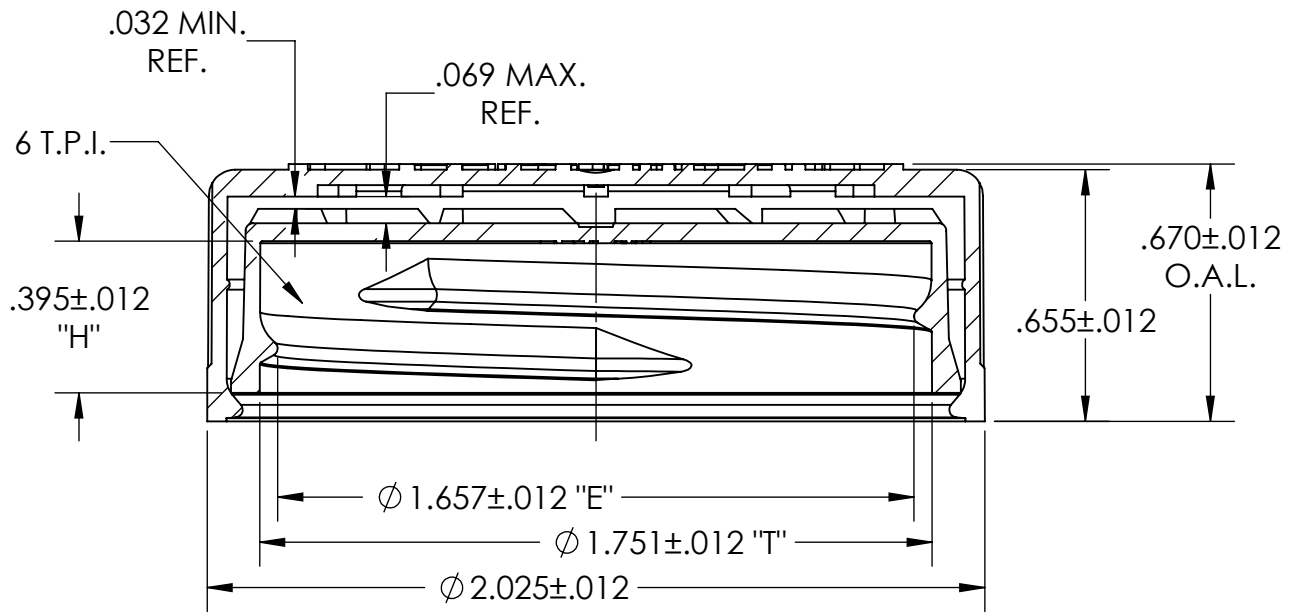


REVISIONS					
DATE	REV.	DESCRIPTION	AUTHOR	DRAWN BY	APPROVED
9/17/21	0	PRELIMINARY	SL	SL	
10/22/21	1	ORIGINAL ISSUE	SL	SL	BK

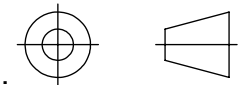


ISOMETRIC VIEW
ACTUAL SIZE



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All dimensions in inches. General tolerances according to DIN 16901.



ORANGE PRODUCTS Inc.
1929 Vultee St,
Allentown, PA, 18103
www.orangeproducts.com

Part name:
45mm-400 CRC

Project name:
45mm-400 CRC

Material:
Polypropylene

Weight:
8.6 ±1.5 gr.

Designed by:
S. Loukov

Approved by:
B. Klotz

<input checked="" type="checkbox"/> INF Issued for Information	<input type="checkbox"/> IFA Issued for Approval	<input type="checkbox"/> IFC Issued for Construction	<input type="checkbox"/> IFP Issued for Production
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Scale	Size	Drawing number	Rev.	Date
2:1	B	45mm CRC	1	10/22/21

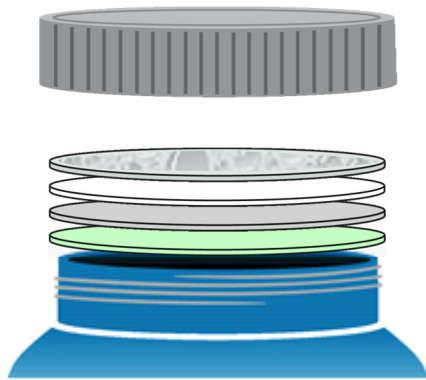
PRODUCT DATA SHEET

HS035/20F

- HS035/20F is a one-piece, polystyrene backed, induction heat seal with an ethylene vinyl acetate based sealant layer that gives a tamper evident bond to Polyethylene (PE), Polypropylene (PP), Polyester (PET), Polystyrene (PS), Vinyl (PVC) and glass containers.
- Available with standard or custom print.

Typical Product Attributes

Construction

		SI (µm)	US (Mils)
Polystyrene Foam		508,0	20.0
White Paper		71,1	2.8
Aluminum Foil		8,9	0.35
Heat Seal		38,1-76,2	1.5-3.0
Thickness Tolerance		± 10%	± 10%
Minimum Width		25,4 mm	1.0 in
Width Tolerance		± 1,6 mm	± 0.0625 in

Properties

Oxygen Transmission (O ₂ TR)	Essentially Zero
Water Vapor Transmission (WVTR)	Essentially Zero

Regulatory Compliance

FDA Compliance	21 CFR 177.1640 Polystyrene and rubber-modified polystyrene. 21 CFR 177.1350 Ethylene-vinyl acetate copolymers. 21 CFR 177.1210 Closures with sealing gaskets for food containers. 21 CFR 176.180 Components of paper and paperboard in contact with dry foods. 21 CFR 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.
Drug Master File (DMF)	002518
Other Compliances	USFDA Food Allergen Guidelines California Proposition 65 Labeling Requirements Limitations of Heavy Metals in Packaging per CONEG & EU 94/62/EC, Article 11
Safety Data Sheet (SDS) Statement	Safety Data Sheets (SDS) are not required for articles as defined in 29 CFR 1910.1200, the OSHA Hazard Communication Standard (HazCom). This product is an article as defined by HazCom and is not considered to be, or to contain, a hazardous chemical based on evaluations made by our company.

Please note that construction does not reflect adhesive or resin bonding layers, if present.

Revision Number: 3
Revised Date: 2018-05-29

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March 13, 2023

Re: FDA 21 CFR Food Contact Status for Tri-Seal HS035/20F Closure Liners

Dear Valued Customer:

This letter is in response to your request for an FDA food safety letter for the Tri-Seal HS035/20F closure liners which we supply to you from Winston-Salem NC and/or Triadelphia WV. Tri-Seal is a TekniPlex business.

All of the components of HS035/20F comply with the applicable FDA regulations for food contact as described in Title 21 (Food and Drugs) of the Code of Federal Regulations.

The overcoat release wax is a fully refined paraffin wax. It complies with 21 CFR 172.886 for use in food and 21 CFR 178.3710 for use in articles in contact with food. The heat seal wax complies with 21 CFR sections 175.105, 175.125, and 175.300 subject to the restrictions on use for each section.

HS035/20F may be used in contact with all Food Types except for fatty foods as the paraffin wax is not to be used for articles in contact with fatty foods. HS035/20F may be used under Conditions of Use B – H. It contains an aluminum foil layer which is a functional barrier for the polystyrene backing.

In regard to current Good Manufacturing Practices (cGMP), our plants will manufacture, pack and store plastic components which meet our customers' quality and sanitation requirements and the applicable FDA regulations in 21 CFR 174.5 and 21 CFR 110 and 210/211.

Therefore, the articles comprising each shipment or other delivery hereafter made by Tekni-Plex to, or on the order of your company, are hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, and not articles which may not, under the provisions of Sections 404, 505, and 512 of the Act, be introduced into interstate commerce.

Please E-Mail me at Ed.McKinley@tekni-plex.com if you have any questions about this matter.

TEKNI-PLEX, INC.



E. L. McKinley

Director, Regulatory Compliance-Americas

elm/HS035FDA-031323