



Selig Group
Technology Department

Customer Converted Product
All Selig Products in Converted Form

Selig Sealing Products, Inc. (Selig) is a world leader in the manufacture of induction closure liners, seals, and other packaging components. Selig has a fundamental interest in that its products are used as designed and intended. However, Selig has no control of the many and varied operations employed by its customers in the conversion of its products. Accordingly, the customer should understand their responsibilities in the conversion of Selig products in order to insure that they are consistent with product design and safety. The purpose of this document is to provide guidance to the customer in the conversion and processing of Selig products. It should be understood that this document is not all-inclusive. The customer is encouraged to consult with Selig for additional information regarding the use of Selig products and specific applications and/or operations.

Document Summary

| | |
|--|-----|
| Customer Notice | 2 |
| Product Conversion and Alteration | 2 |
| Converted Product Storage & Handling | 2 |
| Optimum Storage Conditions (Charts A, B, C and D) | 3-4 |
| Design and Validation | 5 |
| Converted Product Transportation | 5 |
| Selig Medical Application Policy | 5 |
| Disclaimer | 5 |

Customer Notice

Selig strongly encourages its customers to review both their manufacturing processes and their applications of Selig products from the standpoint of Good Manufacturing and the use of First In First Out inventory practices to ensure that Selig products are used only in ways for which they are intended and tested. Selig customer service personnel are available to answer your questions and to provide reasonable technical support. Selig product literature, including technical data sheets, should be consulted prior to use of Selig products. Current product technical data sheets are available from Selig.

Product Conversion and Alteration

- 1) Converted Product' is defined as product that has been altered or processed from its original form as sold and shipped from Selig Sealing Products, Inc., Forrest, Illinois USA., Selig Canada ULC, Aurora, Ontario Canada, Selig UK Ltd., Slough, Berkshire, United Kingdom, and Selig Switzerland LTD, Niederglatt, Switzerland.
- 2) The customer is solely responsible for any alterations of Selig products; this includes but is not limited to: slitting, printing, puncturing, embossing, pre-cutting into disks or other forms, the installation of any device such as a vent or other structure and liner insertion or wadding into closures or other devices.
- 3) The customer is responsible for all conversions of Selig products and that any conversions are consistent with Selig product safety and design.
- 4) The customer is responsible for validating its processes to ensure package application and design integrity.
- 5) The customer is responsible for validating the transportation and handling of converted goods and to ensure their integrity.

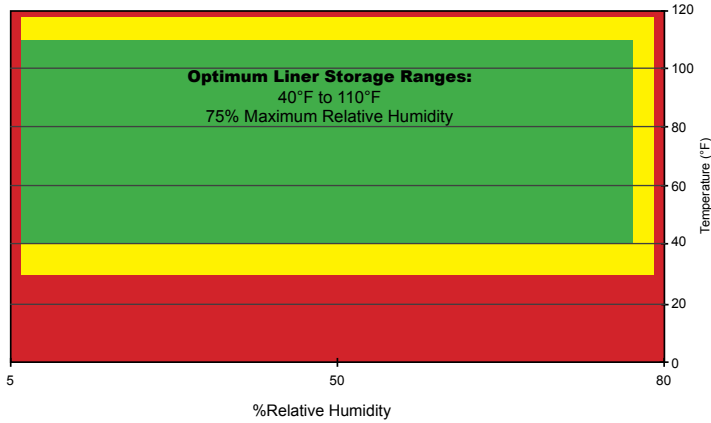
Converted Product Storage & Handling

- 1) Converted products are more susceptible to failure when exposed to conditions of environmental extremes than product in roll form.
- 2) The optimum storage conditions for converted product as liners inserted into closures from rolls or pre-cut liners is 15° - 30° C (60° - 86° F) and relative humidity of 40% - 60%. Optimum storage conditions for converted product as closure liners by product design group with acceptable temperature and relative humidity ranges for each group are defined within the green squares found on Charts A, B, C and D on pages 4-5 of this document. For converted product not otherwise defined or of an unknown group designation, please refer to Chart C.
- 3) Converted product should be protected at all times from any source of contamination that will render the product adulterated and unfit for use.
- 4) Converted product should be used within sixty (60) days to promote first in, first out inventory controls and insure optimum product performance.
- 5) For Selig product shelf life information, please consult the product core labels (for Forrest, Aurora, Slough and Niederglatt manufactured products in roll form) and the product carton labels (for Slough manufactured products in pre-cut disc form) for the Product Expiration Date. Please make note that most Selig products have a shelf life expiry of twelve (12) months from the date of dispatch or shipment although QUADRASEAL™ and PS-113 Torque Activated have expiry of nine (9) months and DELTASEAL™ has an expiry of six (6) months from date of dispatch.
- 6) Specifically concerning board backed DELTASEAL™, if the product is stored at a relative humidity of less than 40% then this increases the likelihood of the board drying out. If the board does dry out, then there is the possibility that the foil membrane on the liner can delaminate from the board backing. The lower the environmental humidity, then the greater will be the possibility that the product can dry out and thus delamination occur. Therefore, Selig strongly recommends that DELTASEAL™ material be protected from a dry environment by storing the material in a plastic bag or covering with plastic sheeting while not being actively processed.
- 7) All Selig products regardless of form should not be stored in direct sunlight or near heat sources such as but not limited to heat exchangers.
- 8) To ensure converted product tracing, closure carton numbers and the Selig product roll serial number used in their production should be documented.

Converted Liners in Closures Optimum Storage Conditions

Chart A - Single-piece foam backed Products: FoilSeal™, Uni-Gard™, C25, Uni-Foam, Lift 'n' Peel™

(°F)



(°C)

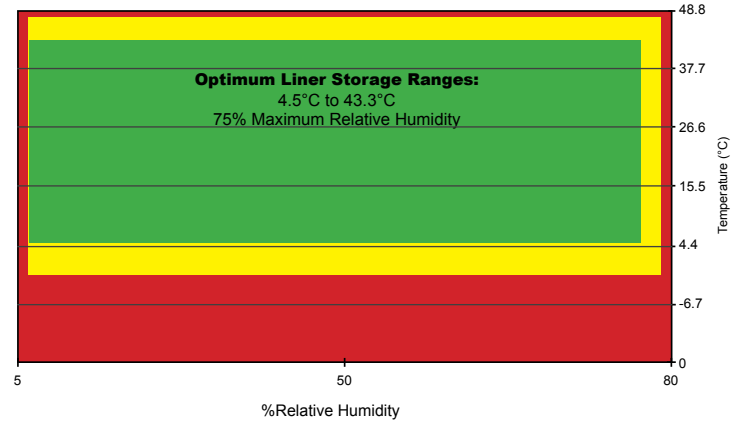
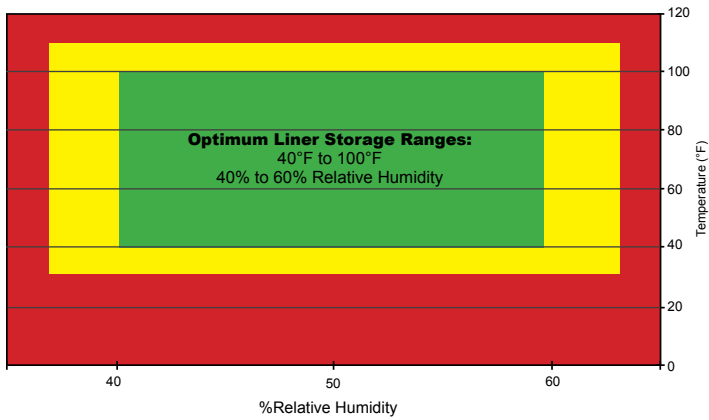
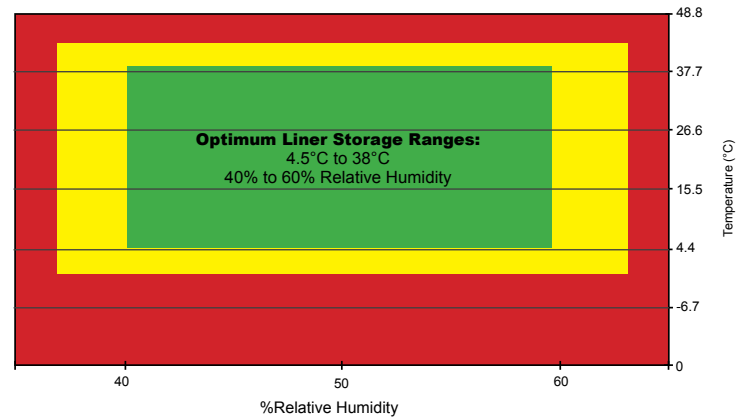


Chart B - All single-piece paper, board, or pulpboard backed products: FoilSeal™, Uni-Gard™, Facings

(°F)



(°C)



Converted Liners in Closures Optimum Storage Conditions (Continued)

Chart C - Two-piece wax or polymer bonded, board or foam backed Safe-Gard™, FoilSeal™, or QUADRASEAL™, foam backed DELTASEAL™, Top Tab™, as well as wax coated and pressure sensitive ALPHASEAL™ and PS-113.

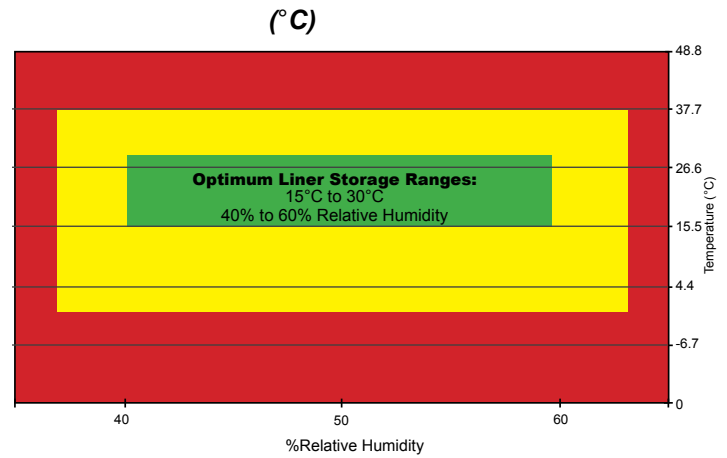
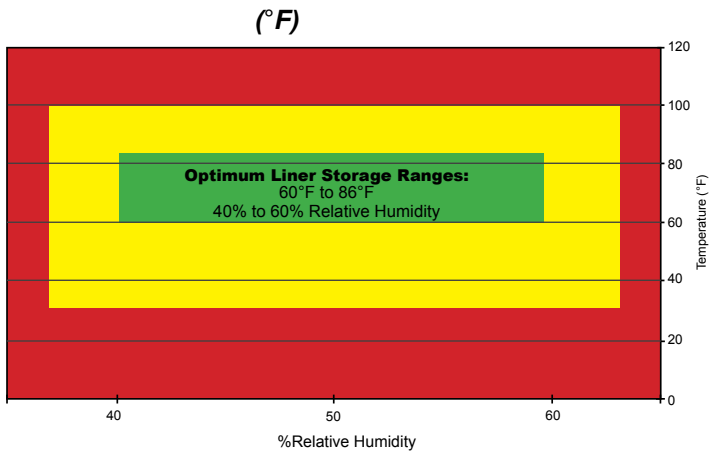
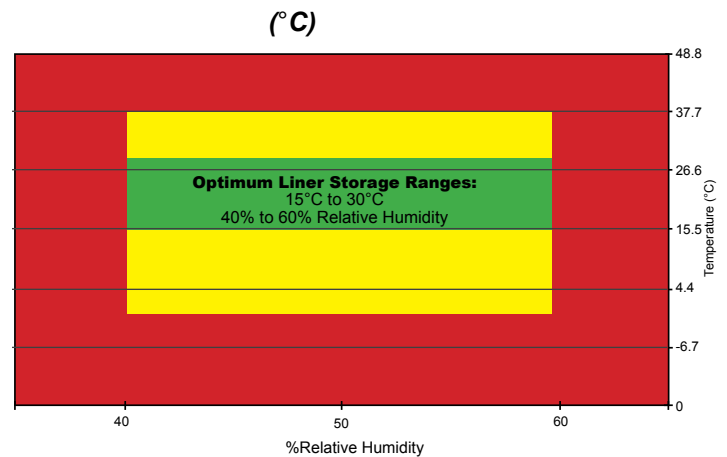
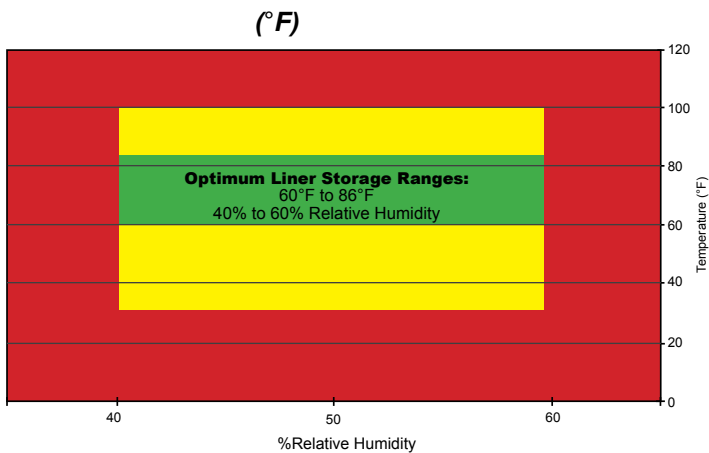


Chart D - Two-piece polymer bonded DELTASEAL™ with pulpboard backing.



Design and Validation

- 1) Selig products are shipped to the customer unadulterated and safe for their intended use per current Good Manufacturing Practices (cGMP) described in 21 CFR Part 110 and Regulation № 2023/2006.
- 2) The customer is responsible for maintaining the integrity of converted product.
- 3) Design and function information for each Selig product is available by referring to Product Data Sheets.
- 4) Validation for specific uses of converted product is the responsibility of the customer.

Converted Product Transportation

In order to ensure converted product integrity, precautions should be used dependent upon the transportation mode employed. As example, when shipping by marine container arrangements should be made to have the container located below deck and in the center of the vessel. Similar concerns should be addressed regarding the environs if shipping by air cargo. In addition, containers and/or trailers should not be allowed to stand in any holding area exposed to extremes in environmental conditions such as may be found in tropical and subtropical environs. Selig is prepared to provide reasonable assistance in any customer transportation and handling validation study.

Selig Medical Application Policy

- Selig will not knowingly sell or sample any product (“Product”) into any commercial or developmental application that is intended for:
- (a) permanent (Long term) contact with internal body fluids or internal body tissues. Long term is a use which exceeds 72 continuous hours;
 - (b) use in cardiac prosthetic devices regardless of the length of time involved; (Cardiac prosthetic devices include, but are not limited to, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices);
 - (c) use as a critical component in medical devices that support or sustain human life; or
 - (d) use in applications designed specifically for pregnant women or designed specifically to promote or interfere with human reproduction.

Additionally, all Products intended for use in pharmaceutical applications, other than pharmaceutical packaging, must pass the current Pharmaceutical Liability Guidelines.

- For the products sold by the Selig, new business opportunities require a business assessment prior to sale or sampling of Selig products.
- Authorized distributors and resellers will adhere to this medical policy.
- Selig does not endorse or claim suitability of their products for specific medical applications. It is the responsibility of the medical device or pharmaceutical manufacturer to determine that the Selig product is safe, lawful, and technically suitable for the intended use. **SELIG MAKES NO WARRANTIES, EXPRESS OR IMPLIED, CONCERNING THE SUITABILITY OF ANY SELIG PRODUCT FOR USE IN MEDICAL APPLICATIONS.**

Disclaimer

NOTICE: Selig assumes no obligation or liability for the information in this document. Because use conditions may differ from one location to another and may change with time, the Customer is responsible for determining whether products and the information in this document are appropriate for the Customer’s use. All statements, technical information, and recommendations are based on tests Selig believes to be reliable, but the accuracy or completeness of the tests is not guaranteed. Selig provides a warranty for products, subject to important limitations and restrictions, all as described in Selig Terms of Sale, which a copy will be furnished to you upon request. **THE WARRANTY CONTAINED IN SELIG TERMS OF SALE IS THE ONLY WARRANTY EXTENDED BY SELIG AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**

NOTICE: If products are described as “experimental” or “developmental”: (1) product specifications may not be fully determined; (2) analysis of caution in handling and use are required; and (3) there is greater potential for Selig to change specifications and/or discontinue production.