LUBRIZOL LIFE SCIENCE

June 15, 2020

Shelf-Life Storage of Medical Grade Thermoplastic Polyurethane Elastomers

Dear Valued Customer:

This letter is in response to your request for written confirmation of the recommended shelf life for Lubrizol Thermoplastic Polyurethanes (TPUs), which includes the following: Pellethane®, Tecoflex™, Tecothane™, Carbothane™, Tecophilic™, Tecoplast™, Tecobax™ and Isoplast® 2500 Series resins and compounds. Our general guidelines for shelf life of our Thermoplastic Polyurethane (TPU) materials, are summarized as follows:

Lubrizol Medical Grade TPUs (Pellethane®, Tecoflex™, Tecothane™, Carbothane™, Tecophilic™, Tecoplast™, Tecobax™ and Isoplast® 2500 Series) should be stored in a cool (below Vicat softening temperature), dry (no standing water) place, out of direct sunlight, in an unopened container. Storage conditions (temperature and moisture) throughout the storage period can affect TPU performance. Lubrizol will provide technical support for our materials for a period of two (2) years from the date of shipping. If a return is approved by Lubrizol, a re-stocking fee may apply. Past this two-year period, Lubrizol will not accept returns of material.

We have enclosed a technical report relative to the long-term storage of Lubrizol's medical grade TPUs. This report will provide additional information to help you define your guidelines for managing the shelf life of your raw materials, such as Pellethane®, Tecoflex™, Tecothane™, Carbothane™, Tecophilic™, Tecoplast™, Tecobax™ and Isoplast® TPU resins and compounds.

Nothing in the foregoing should be construed in any way to modify or amend Lubrizol's standard Terms and Conditions of Sale.

Please contact your Account Representative if you have any questions or comments regarding this information. Thank you for your continued interest in Lubrizol Life Science Health.

Sincerely,
Lubrizol Life Science Health
https://www.lubrizol.com/Health/Medical

Lubrizol

Lubrizol Life Science | Health

Global Headquarters | 9911 Brecksville Road | Cleveland, OH 44141-3201 | USA

LUBRIZOL LIFE SCIENCE

June 15, 2020

Technical Report

Four broad classes of medical grade TPU are made by Lubrizol:

- Polyether-based
- Polyester-based
- Polycarbonate-based
- Isoplast®

As finished products made from TPU age on a shelf[1], the principal mode of deterioration is slow hydrolysis by moisture in the air. Polyether and polycarbonate grades resist this hydrolysis better then polyester grades. A secondary mode of deterioration is oxidation due to ozone or other oxidative agents. This mechanism is very slow when using recommended storage conditions (cool, dry place, out of direct sunlight, in a sealed package).

The mechanism of degradation is cleavage of the TPU polymer chains at ester chemical group bonds and at urethane group bonds when water molecules react[2]. Shorter, lower molecular weight (Mw) chains result. As the polymer chains get shorter (especially as they fall below about 40,000 weight average Mw), properties are adversely affected.

Medical Grade Isoplast® engineered thermoplastic polyurethanes (ETPU) have a unique chemistry to aid in melt processing of the resin into components. This chemistry is highly sensitive to time, heat and moisture and causes the aid in the polymer to degrade, which can affect the properties of the finished product. Once the resin is converted into finished products the deterioration is expected to be similar to polyether and polycarbonate grades.

Recommendations for long term room temperature shelf storage of these four general types of TPU resins are provided below:

- Approximately 3 years for Isoplast® grades in unopened containers (within 2 weeks for opened containers)
- Approximately 5 years for polyester grades
- At least 20 years for polyether and polycarbonate grades

These estimates do not indicate that the samples degrade at these times or are rendered unusable, only that the values of some properties will be affected. Storage and service life of articles manufactured from the various types of TPU should follow similar life expectancies, with further total TPU life limitations being introduced due to processing, mechanical, chemical and environmental influences.

Lubrizol

Lubrizol Life Science | Health

Global Headquarters | 9911 Brecksville Road | Cleveland, OH 44141-3201 | USA

LUBRIZOL LIFE SCIENCE

June 15, 2020

Note: Aromatic type TPUs (e.g. Pellethane®, Isoplast®, Tecothane™, Aromatic Carbothane™) may yellow with age due to their chemical structure. For materials stored in their original packaging and protected from heat and UV light, yellowing typically does not correlate to a negative impact on the physical performance of the material.

[1]For this report, shelf storage refers to articles processed (extrusion, molding, etc.) following recommended TPU practices (proper drying, etc.). Articles are stored in typical containers (cardboard boxes, paper or plastic bags, etc.), average temperatures of 75°F, average R.H. of 50%.

[2]Urethane groups are much more resistant to water attack than ester groups. Polyether TPU grades attain their excellent hydrolytic resistance because they contain only the urethane group bonds.

Lubrizol

Lubrizol Life Science | Health

Global Headquarters | 9911 Brecksville Road | Cleveland, OH 44141-3201 | USA