3M General Offices

3M Center
St. Paul, MN 55144-1000
651 733 1110

2.22.10

Dear Customer:

Thank you for your inquiry regarding the suitability of using 3M skin and wound care products in high-oxygen environments, such as hyperbaric oxygen (HBO) chambers. While there are no current test standards to qualify materials for use in HBO chambers, 3M has worked with an outside professional testing company to identify suitable tests to evaluate the oxygen compatibility of select 3M skin and wound care products by determining the oxygen index (OI) of the products and the response of the products to oxygen exposure testing. Results of this testing support the conclusion that the 3M products tested did not show any evidence of increased flammability when compared to a suitable control material in high oxygen use environments.

The Oxygen Index measures the minimum oxygen concentration in a flowing mixture of oxygen and nitrogen that will just support candle-like burning of the material.

The Oxygen Exposure Test exposes each product to an oxygen-enriched atmosphere (>99.5% oxygen) at elevated temperature (60°C) and pressure (3 atmospheres), and monitors changes in temperature, pressure, and mass of the product for a period of 6 hours. This test measures the potential of a material to self-ignite under conditions typically used in an HBO chamber (including localized regions of high temperature).

Oxygen Index Testing (ASTM D 2863-08)
The OI is the percentage of oxygen that will allow the product to continue to burn longer than 3 minutes or greater than 2 inches downwards from the top of the sample in a glass cylinder at a flow rate of 40 ± 2 mm/s through the cylinder. The following table lists the oxygen index of 3M advanced wound care products compared to a control material (Johnson & Johnson Kling® Roll).

Product	Oxygen Index
3M™ Coban™ 2 Layer Compression System - Comfort Layer	20
3M™ Coban™ 2 Layer Compression System - Compression Layer	20
3M™ Tegaderm™ Ag Mesh Dressing with Silver	18
3M™ Tegaderm™ High Integrity Alginate Dressing	18
3M™ Tegaderm™ Absorbent Clear Acrylic Dressing	20
3M™ Tegaderm™ Foam Dressing (nonadhesive)	23
3M™ Tegaderm™ Foam Adhesive Dressing	20
3M™ Tegaderm™ Hydrocolloid Dressing	21
3M™ Tegaderm™ Matrix Dressing with PHI™ technology	20
3M™ Cavilon™ No Sting Barrier Film*	> 30
Johnson & Johnson Kling® Roll (control)	18

*The 3M™ Cavilon™ No Sting Barrier Film product was tested under ASTM G 125-00, judged by the testing company to be consistent with ASTM D 2863. The oxygen index of this product is of the dried film.

All of the tested products had an oxygen index greater than or equal to the control material.

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Oxygen Exposure Testing

The oxygen exposure test was conducted in a test chamber typically used for determining the autogenous ignition temperature of a material in a pressured oxygen atmosphere (ASTM G 72-01). The testing conditions were designed to simulate the material application environment at its extreme conditions (at 60°C/140°F, 3 atm, 6 hr) while monitoring sample temperature and mass changes. The following table lists the starting and ending masses and temperatures of the 3M skin and wound care products compared to a control material.

Product	Starting, Ending Temp (°C)	Starting, Ending Mass (g)
3M™ Coban™ 2 Layer Compression System - Comfort Layer	63, 60	0.511, 0.516
3M™ Coban™ 2 Layer Compression System - Compression Layer	60, 59	0.503, 0.503
3M™ Tegaderm™ Ag Mesh Dressing with Silver	60, 60	0.503, 0.501
3M™ Tegaderm™ High Integrity Alginate Dressing	59, 58	0.500, 0.485
3M™ Tegaderm™ Absorbent Clear Acrylic Dressing	59, 60	0.520, 0.501
3M™ Tegaderm™ Foam Dressing (nonadhesive)	62, 60	0.511, 0.508
3M™ Tegaderm™ Foam Adhesive Dressing	59, 60	0.500, 0.499
3M™ Tegaderm™ Hydrocolloid Dressing	60, 60	0.522, 0.521
3M™ Tegaderm™ Matrix Dressing with PHI™ technology	60, 59	0.497, 0.479
3M™ Cavilon™ No Sting Barrier Film	59, 59	0.544, 0.452
Johnson & Johnson Kling® Roll (control)	60, 62	0.501, 0.501

The results of the oxygen exposure testing indicate that none of the 11 materials (including control) self-ignited in the 60C, 3 atm pressurized oxygen atmosphere. Temperature and pressure (not shown) data remained relatively unchanged over the 6-hr test duration and were not characteristic of a sample ignition event. The maximum temperature reached by any material was 66C and was the result of normal oscillations of the temperature controller. If a sample would have ignited, it would have exhibited a distinct temperature and pressure increase of the test chamber gas. This was not observed for any of the oxygen exposure tests. No significant mass gains or losses were observed except for the Cavilon™ No Sting Barrier Film product, likely due to the liquid evaporating and outgassing inside the test chamber. Because of this, 3M recommends that any application of Cavilon™ No Sting Barrier Film to the skin be completely dry (a minimum of 30 seconds) before the person enters an HBO chamber.

The individual 3M products did not show evidence of increased flammability when compared to a control material in high oxygen use environments. This testing has been done in a controlled test environment. It is important to consider the overall potential risk profile in your clinical practice.

Please do not hesitate to contact me should you have additional questions. We welcome your comments.

Sincerely,

Joe Tucker
3M Skin & Wound Care Division
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