

RE: PAFS Deterioration - Philips RI

From: Bob Marsh <bobm@polytechinc.com>
To: Lee Lawler <leel@wtbfoam.com>
Cc: Bonnie Peterson <bonnie@polytechinc.com>, Mike Haupt <mikeh@polytechinc.com>
Date: Wed, 23 May 2018 11:33:10 -0400

Thanks. I appreciate your help.
BobM

From: Lee Lawler [mailto:leel@wtbfoam.com]
Sent: Wednesday, May 23, 2018 10:28 AM
To: Bob Marsh
Cc: Bonnie Peterson; Mike Haupt
Subject: RE: PAFS Deterioration - Philips RI

I am sure the degraded foam will not perform well in UL94 testing, though I cannot imagine how one would actually perform the test on such degraded material.

Lee

Lee Lawler | Technical and R&D Manager | Wm. T. Burnett & Co., Foam Division | 2112 Montevideo Road | Jessup, MD 20794 | [o: 410.904.8828](tel:410.904.8828) | [c: 443.416.8354](tel:443.416.8354) | [e: leel@wtbfoam.com](mailto:leel@wtbfoam.com) | [i: www.wmtburnett.com](http://www.wmtburnett.com)

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From: Bob Marsh [mailto:bobm@polytechinc.com]
Sent: Wednesday, May 23, 2018 9:45 AM
To: Lee Lawler
Cc: Bonnie Peterson; Mike Haupt
Subject: RE: PAFS Deterioration - Philips RI

Sorry Lee, but they keep on fishing.

I can only guess to answer this question. Can you help?

Thanks,
BobM

Hi Bob,

As I mentioned we had a few complaints from customers stating that the foam was degrading in our device. We sent samples to a local lab for analysis. They concluded:

EXHIBIT H

WTB 000066

The changes observed in the FTIR spectra collected from the returned samples, indicates an increase in bands that would result from a **cleavage of the bonds in the base polymer**. The physical characteristics of the foam, as observed in the SEM, with indications of embrittlement are consistent with cleavage as well. These results are consistent with an environmental exposure causing base polymer cleavage and embrittlement of the material.

Further investigation concluded that prolonged exposure to high humidity causes the foam to degrade.

The attached are images of:

- 01 Foam installed
- 02 Foam separating
- 03 Foam degrading

As the foam degrades it breaks down into small particulate. A question has been raised regarding the flammability rating of the foam. Does it maintain its UL 94 Flame Resistance rating if it is broken down into particulate?

Thanks,
Vince

From: Bob Marsh
Sent: Friday, May 04, 2018 9:23 AM
To: 'Lee Lawler'
Cc: Bonnie Peterson; Mike Haupt
Subject: RE: PAFS Deterioration - Philips RI

Thanks Lee. I appreciate the comments and perspective. Ill pass them on to the customer.

We have no idea where that statement came from. It has been on our data sheets for probably 20 years. We are removing it.

Have a good weekend!
BobM

From: Lee Lawler [<mailto:leel@wtbfoam.com>]
Sent: Friday, May 04, 2018 9:12 AM
To: Bob Marsh
Cc: Bonnie Peterson; Mike Haupt
Subject: RE: PAFS Deterioration - Philips RI

Hi Bob,

I am unable to answer Question Number 1. We would not recommend using **polyester** foam in such an environment and have no direct data to use to calculate the rate of hydrolysis. **Polyether** foam lifetime would not be expected to reduce significantly at the stated conditions. Use with pure oxygen could shorten the lifetime some by promoting more rapid oxidation. I do not know the extent of the reduction, but do not expect it to be overly significant.

Polyester foam will lose tensile strength and overall integrity as it hydrolyzes. It will eventually decompose to a sticky powder. That will happen very rapidly at 40C, 95% R.H.

Is it one of our data sheets that states foam lifetime being 10 years at 95% R.H? I do not think I have seen a sheet with that statement.

Lee

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From: Bob Marsh [<mailto:bobm@polytechinc.com>]
Sent: Thursday, May 03, 2018 1:43 PM
To: Lee Lawler
Cc: Bonnie Peterson; Mike Haupt
Subject: RE: PAFS Deterioration - Philips RI

Lee,

They are considering still using the ester foam with a scheduled replacement cycle. Can you give an estimate in response to his life expectancy question (below), and express the failure mode (though they are already seeing it in application).

Thanks,
BobM

From: Testa, Vincent [<mailto:vince.testa@philips.com>]
Sent: Thursday, May 03, 2018 1:33 PM
To: Bob Marsh; Bonnie Peterson
Cc: Rob Mays; Tom Yebernetsky
Subject: RE: PAFS Deterioration

Hi Bob,

Thank you for the response. We are evaluating our options regarding the foam. We could switch to the PAF, or we could indicate a preventive maintenance cycle in which they would replace the PAFS foam pieces. Fortunately, the foam is easily accessible. To that point, I need more information about the PAFS foam. The datasheet states the estimated service life is a minimum 10 years at 27C (80F) and 95% R.H. The environmental conditions for our device is a maximum of 40C and 95% R.H. Note the difference in temperature.

1. Please ask your foam supplier to calculate the service life based on this higher temperature (40C vs. 27C).

- a. It would also be useful if they could provide a graph depicting failure over time. For example, if tensile strength reduced over time, they would plot strength vs. time.
2. At the end of the service life, what is the failure mode of this material?

From: Lee Lawler [<mailto:leel@wtbfoam.com>]
Sent: Wednesday, May 02, 2018 2:55 PM
To: Bob Marsh
Cc: Bonnie Peterson; Mike Haupt
Subject: RE: PAFS Deterioration - Philips RI

Bob,

I do not believe that exposure to oxygen will cause any significant damage to polyurethane foam unless elevated temperature and/or humidity is also present.

Lee

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From: Bob Marsh [<mailto:bobm@polytechinc.com>]
Sent: Wednesday, May 02, 2018 11:41 AM
To: Lee Lawler
Cc: Bonnie Peterson; Mike Haupt
Subject: RE: PAFS Deterioration - Philips RI

Lee,

Philips gave us another bit of information. They tested ether vs ester in high heat and humidity and found ether to be the better performer. It validated what we (you) had conveyed. Im going to get back to them, but Id like your input on the oxygen exposure.

Do you think exposing ester or ether foams to higher than ambient oxygen would hasten the deterioration of either. That added to higher temperature and humidity than ambient?

Thanks,
BobM

From: Bob Marsh
Sent: Monday, April 23, 2018 8:02 AM
To: 'Lee Lawler (leel@wtbfoam.com)'
Cc: 'bonnie@polytechinc.com'; Mike Haupt

Subject: FW: PAFS Deterioration - Philips RI
Importance: High

Lee,

You have tried to help us with this before (around August of 2016), and it is back again. The customer is finding degradation of the ester foam and the urethane film in their device, such that particles are breaking off and flowing in the airstream. The customer states (below) what the composite is exposed to. I suspect the temperature is above ambient because of the blower, but I don't think it can be too high since the air goes to a patient's airway (CPAP machine).

We did not receive any feedback from the samples we sent last time, so we do not know if switching to an ether foam would help.

Any thoughts? Does exposure to pure oxygen accelerate ester degradation? Would it do the same for ether? Or for that matter, the urethane film?

Thanks,
BobM

From: Testa, Vincent
Sent: Friday, April 20, 2018 3:06 PM
To: Bonnie Peterson <bonnie@polytechinc.com>
Subject: PAFS Deterioration
Importance: High

Hello Bonnie,

Over the past few years you've helped me with technical questions regarding your foam. Now I have an issue that I'm hoping you can help me resolve. We use the PAFS foam in the air path of our Trilogy family of ventilators as a means for noise reduction (drawings attached). Recently we've received a few complaints from our customers that the foam is disintegrating (images attached, these are separate parts). To me it appears as if the open cell foam is disintegrating. The material sheds and is pulled into the ventilator air path. As you can imagine, this is not a good situation for our users.

I'm wondering what could cause this material to break down. The specification sheet says it has excellent resistance to heat, moisture and chemicals. We do not recommend or specify any means to clean or disinfect this foam. In fact, our device is designed such that these components can be replaced by the customer. Other than room air the only other elements this foam is exposed to normally are isopropyl alcohol and pure oxygen.

Isopropyl alcohol To ease the insertion of the 1044528 into the 1035281 assembly, the vertical walls of the plastic are swiped with alcohol to keep the L4 adhesive from sticking. This is done at our supplier. Note, no alcohol is used in the presence of the 1044529 foam, and these two pieces of foam do not come into contact with each other until final assembly at our facility (well long after the alcohol would have evaporated).
Oxygen Pure oxygen can be ported into the device. It comes into direct contact with both pieces of foam.

Any guidance would be appreciated. We should be able to provide samples if desired. I flagged this message with high importance since we are addressing a potential safety concern.

Thank you,

Vince Testa
Project Mechanical Engineer
Philips Home Healthcare Solutions
1740 Golden Mile Hwy
Monroeville, PA 15146

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