



Eldon James shelf-life determination for products produced with Flint Hills Resources 13R9A polypropylene random copolymer and tubing produced with FX polymer.

Denver, Colorado – August 12, 2016 – Eldon James Corporation – a leading, U.S. based manufacturer of plastic tubing and fittings – announced the successful results of accelerated aging test results for their polypropylene fittings and FX polymer tubing. The tests were intended to define an extended shelf-life for both the polypropylene fittings and FX series tubes ensuring product performance would not be degraded. The exciting news of these results is expected to have a significant impact on the medical industry as well as noteworthy implications to the automotive, food and beverage industry.

BACKGROUND

Eldon James contracted with a third party to complete accelerated aging conditions to an equivalent real time period of ten (10) years. Conditioning for all test samples was completed at 60 degrees C and no more than 20% RH for 323 consecutive days. Per standard accelerated conditioning equations, the combination of the stated exposure temperature, exposure humidity and test duration is equivalent to a real time aging condition of ten (10) years.

TEST RESULTS

Two functional tests were completed to assess the performance of a newly produced fitting/tube assembly (T=0) and a fitting/tube assembly accelerated aged for an equivalent real-time period of ten (10) years (T=10). Tests completed included leak testing and pull testing from the barb fitting.

Leak Testing was completed by pressurizing the tubing/fitting assembly and measuring the air loss from the pressurized cavity. In both cases, T=0 and T=10, the pressure loss was well below the required test criteria. The only difference between time test points was the time at which the measurement was taken directly after the initial pressurization. The T=0 testing was measured directly after pressurization and the T=10 testing was completed after fifteen (15) seconds to. It was determined that during the initial T=0 testing, the tube stabilized dimensionally due to the pressurization and the leakage observed was not leakage but flow into the tube to account for the growing inner diameter and effective volume. Additionally, if measured at times greater than 30 seconds the leak values fell to zero as no leaks are present and the tube has had sufficient time to dimensionally stabilize under pressure. Both tests are considered within specification and performing as intended. See the chart below for test results.



DESCRIPTION	LEAK TESTING (T=0)	LEAK TESTING (T=10)
ACCEPTANCE CRITERIA	9 mL/min Maximum	
SAMPLE SIZE (N)	73	
UNIT OF MEASURE	L/min	
Test Time	After Pressurization	After 15sec Post Pressurization
MIN	0.006	0.001
MAX	0.008	0.001
AVE	0.0069	0.001
S.D.	0.0005	0.000
# PASSED / # TESTED	73/73	73/73

A functional pull test was completed to assess the performance of a newly produced molded luer fitting (T=0) and a luer fitting manufactured and accelerated aged for an equivalent real-time period of ten (10) years (T=10).

Pull Testing was completed using standard barb fittings manufactured by Eldon James. Each connection was pulled to structural failure at a rate of 20in/min per ASTM guidelines for materials with softer durometers and greater elongation potential. Both time points, T=0 and T=10, passed the testing criteria. See the chart below for test results.

DESCRIPTION	PULL TESTING (T=0)	PULL TESTING (T=10)
ACCEPTANCE CRITERIA	4 Lbf Minimum	
SAMPLE SIZE (N)	73	
UNIT OF MEASURE	Lbf	
MIN	9.0	5.18
MAX	11.0	9.32
AVE	10.0	6.70
S.D.	0.365	0.839
# PASSED / # TESTED	73/73	73/73



Dimensional analysis of the T=10 aged product was completed to assess the dimensional stability of the tubing. Both tubing inner diameter and outer diameter were measured for all test samples. All samples passed the critical dimension criteria set forth by the design drawings. See chart below for the dimensional results.

DESCRIPTION	DIMENSION	
	Inner Diameter	Outer Diameter
ACCEPTANCE CRITERIA	.047 ± .003	.110 ± .003
SAMPLE SIZE (N)	73	73
UNIT OF MEASURE	In	In
MIN	.044	.107
MAX	.047	.110
AVE	.046	.109
S.D.	.0006	.00061
# PASSED / # TESTED	73/73	73/73

Dimensional analysis of the T=10 aged product was completed to assess the dimensional stability of the molded luer fittings. Various dimensions were measured for all test samples. All samples passed the critical dimension criteria set forth by the design drawings. See chart below for the dimensional results.

DESCRIPTION	DIMENSION			
	Thru Hole	Barb Length	Length	Outer Diameter
ACCEPTANCE CRITERIA	.041 ± .018	.092 ± .018	.585 ± .023	.445 ± .023
SAMPLE SIZE (N)	73	73	73	73
UNIT OF MEASURE	In	In	In	In
MIN	.041	.088	.583	.440
MAX	.044	.095	.588	.444
AVE	.042	.090	.585	.442
S.D.	.0009	.0014	.0014	.0005
# PASSED / # TESTED	73/73	73/73	73/73	73/73



CONCLUSION

All testing was conducted in accordance with the methodology set forth in the testing protocol and test results indicate that the established acceptance criteria were met.

Eldon James' FX polymer and molded products produced with 13R9A polypropylene polymer has passed ten (10) year accelerated aging and as such should have **a shelf-life of ten (10) years AFTER processing into product configurations.**