ANDERSEN PRODUCTS	Andersen Products Lab Report			
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Lab Address: 3202 Caroline Dr. Haw River, NC 27258				
Test Name: Reduced Residual of AN11 Nasogastric Tubes				

Background:

On September 10, 2015, the French Agence Nationale de Sécurité du Médicament[1] (ANSM) issued a "Health Policy Decision". This decision amends the requirement of the EN ISO 10993-7 standard regarding residual ethylene oxide levels on medical devices (MD) intended for use on premature neonate, neonate and infant patients. The decision states that:

> ***"The ANSM considers that the harmonised standard NF EN ISO 10993-7 specifying the allowable limits of residues from sterilisation with ethylene oxide (EO) is flawed when applying to medical devices for the treatment of patients with a body mass different from 70 kg and for whom more than 5 MD sterilised with EO are used simultaneously. Therefore, application of the standard alone is not sufficient to demonstrate compliance with the essential requirements related to the control of residues from EO sterilisation for MD used in the care of premature neonate, neonate and infant patients."***

The decision proposes new, lower EO residual levels for MD used in the case of these smallest patients. The strictest interpretation of the new standard requires pediatric medical devices to have less than 0.028 mg of Ethylene Oxide (EO) when measured over a 24 hour period and less than 0.86 mg present on the entire device (exhaustive extraction).

Summary:

Two studies were performed to determine the total aeration time required for Andersen Products' AN 11 Pediatric Nasogastric tube to meet new, more stringent ANSM residual standards. For these tests the aeration period for these tubes was increased from 12 to 18 days after EO sterilization.

The first test was performed at Andersen Products Lab to determine the amount of EO extracted from the AN 11 tubes in a 24 hour period. A 24 hour DI water extraction was performed. Less than 0.009mg of EO were detected on the devices, well below the ANSM limit of 0.028.

For the second test, new samples were sent on dry ice to a third party lab to determine the total amount of EO present on the devices. An exhaustive thermal air extraction was performed. A total of 0.04mg of EO was found on the devices, well below the ANSM limit of 0.86mg.

Based on the test results, increasing the aeration time from 12 to 18 days provides sufficient aeration to exceed the new ANSM standard.

Table 1 ANSM Proposed New Residual Standards

	Patient weighing 70 kg		Patient weighing 1 kg 2 possible interpretations of the standard	
Admissible limits for EO/MD prolonged exposure	**Calculation according to Annex G of the standard**	**Values presented by the standard in §4.3.3**	**Pro rata calculation / 70 kg from §4.3.3**	**Calculation according to Annex G to the standard**
Average/day	4.2 mg/day	2 mg/day	0.028 mg/day	0.06 mg/day
Max over 24 h	4.2 mg	4 mg	0.028 mg	0.06 mg
Max over 30 days (average/day x 30 days)	126 mg	60 mg	0.86 mg	1.8 mg

[1] French National Agency of Medicines and Health Products Safety
http://ansm.sante.fr/content/download/85793/1081953/version/1/file/Doc+_+DPS_+ethylene-oxide_EN-feb2016.pdf

Method and Results

The aeration time for the AN 11 Pediatric Nasogastric tube was increased from twelve days to eighteen days. The tubes were tested for residuals (see Table 1) in Andersen Laboratory. A 24 hour extraction was performed in DI water at 35-40°C. The EO detected was less than 0.009 mg/sample.

A second AN 11 tube was aerated for eighteen days. Samples were placed in a cooler with dry ice and sent to a third party lab for testing. A thermal air, exhaustive extraction was performed. A total of 0.04mg of EO was found on the device.

Table 2 Andersen Lab Residual

Final Results:				
Sample ID	EO Residual (ug/g)	EO Residual (ppm, w/w)	Sample Weight (g)	EO Residual (mg/sample)
A	<0.9	<0.9	10.325	0.0094
	<0.9	**<0.9**	**10**	**<0.00944**

Table 3 Wuxi Apptec Residual

Sample ID	EO Residual (ppm)	EO Residual (mg)
1	3.9	0.04

Conclusion:

Based on the studies performed, increasing the aeration period for AN 11 pediatric nasogastric tubes from 12 to 18 days yields residual levels that are significantly below the new limit set by ANSM.

Signatures:

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