U.S. Department
of Transportation
**Research and
Special Programs
Administration**

FEB 13 2003

400 Seventh St., S.W.
Washington, D.C. 20590

Mr. Alastair Hayton-Williams
Sales and Marketing Consultant
First Filtration International Co., Ltd.
37/2 Moo 9, Sukhumvit Road
Banglamung, Chonburi
20260 Thailand

Reference No. 02-0264

Dear Mr. Hayton-Williams:

This is in response to your letters and additional information concerning your product, the Aqui-Pak pouch. You described the product as being made of a multi-layered, absorbent, disposable polymeric material. You state that the pouch provides separation, absorption and cushioning in one product and can be used as the secondary packaging for liquid primary receptacles. You also state that a liquid upon contact with the polymeric material is completely absorbed and becomes a gel. We have paraphrased your questions. We apologize for the delay in responding and any inconvenience this may have caused.

Q1. Must our Aqui-Pak pouch be tested by the Research and Special Programs Administration (RSPA) or other company to be approved as a packaging component for a diagnostic specimen under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180)?

A1. The answer is no. The secondary packaging is not required to be tested as an individual component but as part of the complete packaging. RSPA does not test or certify hazardous materials packagings.

In a recently published final rule, we adopted new § 173.199 to the HMR to permit a diagnostic specimen other than Risk Group 4 to be transported in a non-DOT specification triple packaging consisting of a primary receptacle, a secondary packaging, and an outer packaging (Docket No. RSPA-98-3971 (HM-226), August 14, 2002, copy enclosed). This section requires that the primary receptacle and the secondary packaging be properly packed and secured and that the secondary packaging be leakproof. The completed packaging must also be capable of passing a 1.2 meter (3.9 feet) drop test as prescribed in § 178.603. If intended for the transport of liquids by aircraft, § 173.199(b)(4) requires that the primary receptacle or secondary packaging be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi). It is the shipper's responsibility to ensure that the packaging or container is an authorized packaging and meets all applicable requirements.

020264

173.199

A Risk Group 4 diagnostic specimen must be classed and transported as a UN 2814 or UN 2900 infectious substance in a packaging tested and marked as required by § 173.196 and § 178.503(f), respectively. See §173.134(a)(4). The new requirements become effective February 14, 2003; however, voluntary compliance is authorized.

Q2. Our Aqui-Pak pouch conforms to Packing Instruction 650 of the International Civil Aviation Organization's Technical Instructions for the Transport of Dangerous Goods by Air (ICAO Technical Instructions). Specifically, four samples can be placed alongside each other while allowing each to be in its own absorbent pouch. As such, do we need to take any further steps to qualify our material as an authorized non-bulk secondary packaging?

A2. If, as you state, the combination packaging containing the Aqui-Pak pouch conforms to Packing Instruction 650 of the ICAO Technical Instructions, the answer is no. However, the completed secondary packaging must meet all applicable requirements.

I hope this satisfies your request.

Sincerely,

Hattie L. Mitchell

Hattie L. Mitchell, Chief
Regulatory Review and Reinvention
Office of Hazardous Materials Regulation

Enclosures

INFOCNTR

From: Alastair [eightwestfour@hotmail.com]
Sent: Wednesday, October 02, 2002 1:39 AM
To: Infocntr, Infocntr <RSPA>
Subject: Fw: OHMS\Aqui-Pak

Edmonson
§173.134 199
Diagnostic Specimen
~~Regulated Medical Waste~~
02-0264

Sorry! Last letter sent without attachments.

Mr. Edward T. Mazzullo
Ms. Susan gorsky
Office of Hazardous Materials Standards
U.S. DOT/RSPA (DHM-10)
400 7th Street S.W.
Washington, D.C. 20590-0001

Dear Mr. Mazzullo and Ms. Gorsky,

Transportation of Diagnostic Medical Specimens

We are writing to you as we would greatly appreciate your advice and assistance concerning a material used for transporting hazardous liquids, serum and medical specimens. You can see on our web-site the most recent article concerning **Safebox** and the **Royal Mail (Great Britain).** We manufacture the insert for Safebox -- **Aqui-Pak**. Aqui-Pak is a super-absorbent disposable material for the safe transportation of hazardous liquids and diagnostic specimens, including blood and urine. This concept is of immense interest to those concerned with safety in the courier and mailing companies, medical and veterinary professions and to anyone involved in taking and transporting samples. You can also see the magazine in which our press release was published and photographs of both Aqui-Pak and Safebox on our Web-site.

There is strong interest in this product from companies in USA, and we would very much like to know if our material has to be tested by you, or whether it is tested in conjunction with the outer packaging supplied by the client company.

The material was developed following requests from couriers and the postal service in Great Britain for use by hospitals, laboratories, drug and alcohol testers, veterinarians and police stations although there are many other applications and uses. No doubt you may have other ideas. The pouch form costs only a few US cents.

The directive P650 is also on our web-site, which relates to UN 3373 concerning packaging materials used in the transportation of diagnostic specimens. Aqui-Pak conforms to these specifications, particularly by allowing the four samples to be places alongside each other yet separated in the totally absorbent pouch. As such, do we need to take any further steps?

Our new web address is www.firstfiltration.com

Thank you for your assistance.

Yours sincerely

Alastair Hayton-Williams

Sales and Marketing Consultant
First Filtration International Co. Ltd.