

Packaging: Liquivent® Lavage Solutions are supplied sterile in polymeric syringes and vials. Product is aseptically filled into pre-sterilized, non-pyrogenic containers.

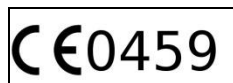
Storage Instructions: Store between 15-30°C. Protect from impact, light, and moisture. (PFB: Freezing Point is 6°C and boiling point is 142°C)

USA: For Research Use Only

Complaints: Any user/customer who has a complaint or is dissatisfied with the quality, identification, reliability, safety, efficacy, and/or performance of the product should notify OriGen Biomedical or its authorized distributor. In the event of an incident or risk of a serious incident liable to result in, or to have resulted in, the death or serious deterioration in the health condition of a patient or user, OriGen Biomedical or its authorized distributor should be immediately warned by telephone, fax or letter. All complaints should be accompanied by the name(s), reference(s), and batch number(s) of the component(s) and the name and address of the claimant, the nature of the complaint with as much details as possible and the indication of a requested response.

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OriGen Liquivent® Lavage Solutions

Instructions for Use: Caution: These instructions should be read and understood by all personnel before using the device.

Intended Use: Liquivent® solutions are indicated to be used as an aid in removing debris, secretions and foreign matter from the lungs and bronchial system. For single use only.

USA: For Research Use Only

Contraindications: Contraindicated for other uses.

Product Code	X-ray	Package
PFB-3	Radiopaque	3.2 ml vial
PFB-50	Radiopaque	50 ml syringe

Product Description: Liquivent® (Product code **PFB**) is pharmaceutical-grade Perfluorooctylbromide ("Perflubron"), C₈BrF₁₇, is **radiopaque**, and of 98% or greater purity. The balance is other fluorocarbons. Contains no Phthalates, BPA, animal products, or latex.

Warning:

- This product is for single use only. Recovery of the product from the patient is likely to be virally and bacterially contaminated, and this product cannot be re-sterilized. Re-use of the product can cause sepsis, viral transmission, hematological complications, and patient death.
- Not for Injection, admixture or IV use.
- Do not use if package is opened or damaged.

Lavage, General

1. Liquivent is referred to as Perfluorocarbons (PFC) in the following instructions.
2. PFC Lavage is useful for removing accidentally aspirated liquids from the lungs, including meconium [4] because PFCs are immiscible with water. Due to their high density, PFCs are also useful for removing fine solids, such as charcoal, which will float to the top of the PFC column.
3. PFC Lavage may also be useful in helping to remove thick lung secretions. [2]

Directions for Use:

1. PFC should be introduced directly into the lungs through an endotracheal tube or bronchoscope. Bottles may be poured into the endotracheal tube or drawn up in sterile syringes and instilled into the trachea. Fill lungs to Tracheal Carina, approximately 10ml/kg [2].
2. Lavage action is primarily through density as the PFCs are twice as dense as water (2g/cc), and many commonly aspirated materials will float to the top of the PFC column. [4].
3. Suction off the debris which floats to the top of the PFC column. After allowing time for the lavage agent to work, suction out the remaining PFC in the usual manner. Remaining PFCs will evaporate through normal respiration or ventilation [1].

Clearance from the Body:

1. Liquivent® has a very high evaporation rate, with radiographic clearance of most PFCs in about 48 hours [1].
2. Trace amounts escaping from the lungs can remain in the lymphatic or GI system. Beyond lingering radiographic imaging, there are no known side effects of exposure to PFCs [1, 3, and 5].

References

- 1) Reickert, CA, et al. The pulmonary and systemic distribution and elimination of Perflubron from adult patients treated with partial liquid ventilation. *Chest* 119:515-522; 2001.
- 2) Lindemann, R. Bronchioalveolar lavage with perfluorochemical liquid during conventional ventilation. *Pediatr Crit Care Med* 2007 Vol 8(5):486-8.
- 3) Noveck R. Randomized safety studies of intravenous Perflubron emulsion II; Effect on immune function in healthy volunteers. *Anesthesia and Analgesia* 91:812-22; 2000.
- 4) Marraro G, et al. Perfluorocarbon broncho-alveolar lavage and liquid ventilation versus saline broncho-alveolar lavage in adult guinea pig experimental model of meconium aspiration. *Intensive Care Med*. 24:501-508; 1998
- 5) Hagerty, R. Radiographic detection of Perflubron fluoromediastinum and fluororetroperitoneum nine years after partial liquid ventilation. *Am Soc Emergency Radiol*, Oct 2007