

Film Preserves Blood Substitute

Transparent laminate prevents oxygen and moisture loss.

To make the blood supply safer, more economical, and easier to manage, Toronto-based Hemosol Inc. has developed a blood substitute product, Hemolink. Currently in clinical trials, Hemolink is manufactured from highly purified human hemoglobin taken from outdated blood at the Red Cross's blood bank. It passes through two virus-removal processes during manufacturing to virtually eliminate viral contamination. Hemolink is compatible with all blood types and offers a long product shelf life at normal storage temperatures, which could help alleviate the periodic shortages of donated blood and result in more effective, less costly management of the blood supply. "We're hoping to be licensed and marketing Hemolink by late 2000 or shortly thereafter," says Dirk Alkema, Hemosol's vice president of manufacturing.

To maintain a long shelf life, Hemosol needed to find a packaging material that minimizes gas exchange and moisture loss. "Like allogeneic blood, our highly purified blood product delivers oxygen," explains Peter Wojciechowski, manager of process development. "Since the product is very sensitive to oxygen, we have to keep gas permeability to a minimum." The firm also wanted to use a transparent film in order to make the substitute resemble real blood. "Clear packaging helps improve the market's acceptance of this new product since donated allogeneic blood also comes in clear packaging," says Wojciechowski.

"We searched for the highest levels of oxygen and moisture barrier properties available in a clear laminate so that we could maintain the stability of the product," says Alkema. When Hemosol

approached Rollprint Packaging Products (Addison, IL) with their packaging objectives, Rollprint began developing their highest-barrier ClearFoil laminate to meet the needs of the blood substitute product. The firm ended up creating a



The ClearFoil® overpouch allows users to see the product.

new laminate in the ClearFoil® family using ClearFoil SiOX-F sandwiched between a 2.5-mil sealant layer and a 75-gauge oriented polypropylene outer layer. The laminate features an oxygen permeability of only 0.003 cm³/100 sq in./day at ambient temperatures and under normal atmospheric pressure. "That level of oxygen barrier represents 130 times more protection than the next-best laminate we found, and that offered a permeability of 0.04 cm³," says Sam Teleki, special projects manager at Hemosol.

Finding a water vapor barrier was also important to Hemosol because moisture loss can affect product concentration. The ClearFoil SiOX-F laminate provides a water vapor permeability of only 0.02 g/100 sq in./day,

thus protecting the product's hemoglobin concentration. "As we were analyzing the permeability of a variety of flexible films, we were looking for maximum barrier levels primarily to maintain product quality," Teleki explained. "We recognized that with high barrier properties, we could also increase the product shelf life at higher product storage temperatures." Compared to allogeneic blood that has a shelf life of less than 42 days, Hemolink, when packaged in the ClearFoil SiOX-F overpouch, offers far greater product stability. "Although our data aren't finalized, the shelf life of our product looks very good," Alkema noted. "Our target is at least a two-year shelf life for Hemolink stored at 4°C and a one-year shelf life for product stored at ambient temperatures. The ClearFoil overpouch will help us achieve that target."

Transparency was also important. "Given our need for high barrier levels, the obvious choice was to go with foil, but we wanted to be able to see the product through the package," Wojciechowski states. "The clarity of the ClearFoil overpouch allows us to see the product to help ensure product quality before we ship. It also gives clinicians the chance to visually inspect the product prior to use."

Hemosol now packs its Hemolink-filled IV infusion bags into overpouches made of Rollprint's ClearFoil SiOX-F laminate. "With market demand projections for a blood substitute product in North America pegged at three million units a year, we anticipate a significant role for Rollprint in Hemosol's success," says Alkema. 