

**TABLE 9.3 (Continued)**  
Composition of Approved Biological Products

| Product  |   | Composition |
|--|---|-------------|
| Dacalizumab is humanized IgG1 MAbs with MW of approximately 144 kDa.   | Each milliliter contains 5 mg of Dacalizumab and 3.6 mg of sodium phosphate monobasic monohydrate, 11 mg of sodium phosphate dibasic heptahydrate, 4.6 mg of sodium chloride, 0.2 mg of polysorbate 80 and may contain hydrochloric acid or sodium hydroxide to adjust the pH to 6.9. No preservatives are added.   |             |
| Darbepoetin alpha is a 165-amino acid protein that differs from recombinant human erythropoietin in containing five <i>N</i> -linked oligosaccharide chains, whereas recombinant human erythropoietin contains three. The two additional <i>N</i> -glycosylation sites result from amino acid substitutions in the erythropoietin peptide backbone. The additional carbohydrate chains increase the approximate MW of the glycoprotein from 30,000 to 37,000 Da. | Two formulations contain excipients as follows: polysorbate solution contains 0.05 mg of polysorbate 80, 2.12 mg of sodium phosphate monobasic monohydrate, 0.66 mg of sodium phosphate dibasic anhydrous, and 8.18 mg of sodium chloride in water for injection, USP (per 1 mL) at pH 6.2 ± 0.2. Albumin solution contains 2.5 mg of albumin (human), 2.23 mg of sodium phosphate monobasic monohydrate, 0.53 mg of sodium phosphate dibasic anhydrous, and 8.18 mg of sodium chloride in water for injection, USP (per 1 mL) at pH 6.0 ± 0.3. |             |
| Denileukin diftitox, a rDNA-derived cytotoxic protein composed of the amino acid sequences for diphtheria toxin fragments A and B (Met 1-Thr 387)-His followed by the sequences for interleukin-2 (IL-2; Ala 1-Thr 133) and has a MW of 58 kDa.  | Each 2 mL vial contains 300 mcg of recombinant denileukin diftitox in a sterile solution of citric acid (20 mM), EDTA (0.05 mM), and polysorbate 20 (<1%) in water for injection, USP. The solution has a pH of 6.9–7.2.  |             |
| Dornase alpha, rhdNase, a glycoprotein that contains 260 amino acids with an approximate MW of 37,000 Da.  | The aqueous solution contains 1.0 mg/mL of dornase alpha, 0.15 mg/mL of calcium chloride dihydrate, and 8.77 mg/mL of sodium chloride. The solution contains no preservative. The nominal pH of the solution is 6.3 and is used as nebulizer.   |             |
| Drotrecogin alpha (activated) is a glycoprotein of approximately 55 kDa MW, consisting of a heavy chain and a light chain linked by a disulfide bond.  | Each vial contains 5 and 20 mg drotrecogin alpha and 40.3 and 158.1 mg of sodium chloride, 10.9 and 42.9 mg of sodium citrate, and 31.8 and 124.9 mg of sucrose, respectively.  |             |
| Efalizumab is humanized IgG1 kappa isotype, monoclonal, and has a MW of approximately 150 kDa.   | Each single-use vial contains 150 mg of efalizumab, 123.2 mg of sucrose, 6.8 mg of L-histidine hydrochloride monohydrate, 4.3 mg of L-histidine and, 3 mg of polysorbate 20 and is designed to deliver 125 mg of efalizumab in 1.25 mL.   |             |

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