**Formulation Record**

**Name:** Cold Cream

**Strength:** Base

**Dosage Form:** cream

**Route of Administration:** Topical

**Date of Last Review or Revision:** 08/18/05

**Person Completing Last Review or Revision:** Robert Shrewsbury

**Formula for 1,000 grams of product**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Quantity</th>
<th>Physical Description</th>
<th>Solubility</th>
<th>Therapeutic Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>cetyl esters wax</td>
<td>125 g</td>
<td>white to off-white translucent flakes, faint odor, bland taste</td>
<td>insoluble in water, soluble in hot alcohol, chloroform, ether, and fixed oils</td>
<td>texturing agent</td>
</tr>
<tr>
<td>white wax</td>
<td>120 g</td>
<td>white, soft to brittle wax, slight balsamic taste, honey-like odor</td>
<td>practically insoluble in water, soluble in hot alcohol, chloroform, benzene, ether</td>
<td>stiffening agent</td>
</tr>
<tr>
<td>mineral oil</td>
<td>560 g</td>
<td>colorless, transparent, oil liquid; tasteless, odorless</td>
<td>insoluble in water and alcohol</td>
<td>internal – laxative; external – emollient, texturing agent</td>
</tr>
<tr>
<td>sodium borate</td>
<td>5 g</td>
<td>hard crystals, or granules, efflorescent in dry air</td>
<td>1 gm in 16 ml of water or 1 gm of glycerol; insoluble in alcohol</td>
<td>preservative; alkalizing agent</td>
</tr>
<tr>
<td>Purified water</td>
<td>190 ml</td>
<td>colorless, transparent liquid, tasteless, odorless</td>
<td>N/A</td>
<td>vehicle</td>
</tr>
</tbody>
</table>

**Example Calculations:**

Specific gravity of mineral oil = 0.88

**Equipment Required:**
- Class A prescription balance
- hotplate, thermometer
- 2 small beakers
- glass stirring rod

**Method of Preparation:**
1. Using the prescription balance, weigh the solid ingredients.
2. If necessary, reduce the cetyl esters wax and the white wax to small pieces.
3. Melt the cetyl esters wax and the white wax in a beaker using a hot plate.
4. Add the mineral oil and continue heating the mixture until it reaches 70°C.
5. Dissolve the sodium borate in the purified water, which has been warmed in a second beaker to 70°C.
6. Add the warm aqueous mixture gradually to the melted oleaginous mixture.
7. Remove the resulting mixture from the heat; stir rapidly and continuously until the mixture has congealed.
8. Package in ointment jar. Provide a professional finish.

**Description of Finished Product:**
Uniform, luminescent white cream with no visible particles; spreads easily without a gritty texture.

**Special Note:** Product will not reach final form for several hours.
Quality Control Procedures:
Observations for uniform consistency
Weight of final product.

Packaging Container:
Package in appropriate size plastic ointment jar.

Storage Requirements:
Store at room temperature.

Beyond-Use Date Assignment:
USP Guidelines:
All other formulations (i.e., not a solid, not a liquid): Thirty days or intended duration of therapy, whichever is less.

Label Information:
External Use Only

Source of Recipe:
Pharmaceutics Laboratory Web page: pharmlabs.unc.edu

Literature Information:
Applied Pharmaceutics and Contemporary Compounding, Chapter 9, Dermatological Formulations: Ointments and Pastes.