SHELLAC
A Versatile Film Coating System

• Sensient
  • Sensient’s fully formulated coating systems
     • Spectrablend
     • Spectrablend II
     • Spectrafilm
     • Spectrablend CC (Calcium Carbonate)
     • Spectrablend MB (moisture barrier)
     • Protect EN
       • Shellac-based formula

• Shellac
  • Shellac as a natural versatile resin
     • About Shellac
     • Offers tablet coating benefits
     • Functional properties
       • Enteric
       • Sealant
       • Barrier protection
       • Taste & odor masking
       • Aesthetic and immediate release properties

DISCUSSION OVERVIEW
HS2  period after protection
Houston Smith, 3/28/2013
Sensient Pharmaceutical is a global leader in superior coating systems, brand-defining color solutions, and enhanced product performance for the pharmaceutical and nutraceutical markets.
Spectrablend™
A customizable, fully formulated film coating system that consists of film forming polymer(s), plasticizer, and colorant.

Spectrablend II™
A customizable, fully formulated film coating system that provides additional benefits to Spectrablend.

Spectrablend CC™
A low-dust, high solids, titanium dioxide-free, opaque coating system.

Protect™
An enteric, aqueous coating system optimized for use on tablets, soft gels, and two-piece hard capsules.

Spectrafilm™
A customizable, pre-blended color system.

About Shellac
Shellac, also known as Lac, is cultivated in various countries:
- India
- Thailand
- China
- Vietnam

It takes about 300,000 lac bugs to make 1 kg of shellac flakes.
comma after India
Houston Smith, 3/28/2013
### ABOUT SHELLAC

- Laccifer Lacca Kerr (Family Coccidae) insects secrete resin on bark (Lac Host) and protect themselves into the adult stage by forming cocoons.

- The female lac insects are wingless; however, the male insects swarm impregnating female lac insects and then die.\(^7\)

- After impregnation, they attach pincers under the bark of the host trees to feed while depositing & forming the cocoon of lac resin around them from cranial glands.

### ORIGIN

- The stick lac covered branches are pruned from the host trees and sent for processing.

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### ABOUT SHELLAC

- The Lac encrustations removed from the bark (sticklac/grainlac) is washed in an aqueous media to remove excess erythrolaccin & laccaic acid (red dyes) from the sticklac then filtered and dried.

  - Historically, colonial ‘British Red Coats’ used Laccaic acid to dye uniforms red.

  - Today, Laccaic acid is sold principally to the Japanese market for use in dyeing ketchup.

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*Image reference*\(^4\)
### ABOUT SHELLAC

#### PROCESSING METHODS

<table>
<thead>
<tr>
<th>Seedlac</th>
<th>Three principle processing methods:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Heat</td>
</tr>
<tr>
<td></td>
<td>Solvent - (De-Waxing)</td>
</tr>
<tr>
<td></td>
<td>Bleached</td>
</tr>
</tbody>
</table>

**Heat Processing**

Seedlac is heated, filtered and then forced through rollers forming thin sheets, dried & broken into flakes.

**Solvent Extraction (De-Waxing)**

Seedlac is refluxed with ethanol for an hour, filtered, and then carbon treated to decolorize the shellac. Ethanol is then removed and the shellac is sent through rollers - dried sheets are then flaked.

**Bleached Processing**

Seedlac is made alkali-soluble, filtered then bleached with sodium hyperchlorite. Shellac is precipitated from dilute sulfuric acid, filtered & water washed. The shellac is dried, and ground into a white powder.

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**Processed Shellac**

![Processed Shellac Images]
• **Shellac**: esters of polyhydroxy carboxylic acids

• **The Ester of Shellac** (image to the right)
  - Main components are:
    - Aleuritic Acid (35%)
    - Jalaric Acid (25%)
    - Shellolic Acid (8%)
    - Butolic Acid (8%)

• **Aleuritic Acid**
  - Perfume manufacturers substitute Civitone with extracted Aleuritic Acid

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• Pharmaceutical & Nutraceutical Industries
  - Enteric: intestinal release *(acidic properties resist stomach acids)*
  - Sealant
  - Decreased moisture permeation
  - Masking taste and odor,
  - Immediate release & aesthetic film properties

• Industrial Uses: Sealant, Lacquer – primer for wood

• Food Industry: Candies – Sealant, coating, oxygen barrier for fruits & glaze
HS3  acids3?
     Houston Smith, 3/28/2013

HS4  colonic release? I thought it was intestinal release?
     Houston Smith, 3/28/2013
Shellac – Product Diversification
• Pharmaceutical
• Nutraceutical

Polymers used in enteric shellac coating systems:
• Polyvinyl alcohol, (PVA) – Results: in film cracking and water diffusion
• Hydroxypropyl methylcellulose (HPMC) – Results: Increases the film voids which increases the drug release
• Carbomer 940 – Results: Swells leading to diffusion and premature drug release
• Sodium Alginate – Results: Passes USP enteric testing

Experimentation
• De-waxed & De-colorized shellac NF (de-waxed orange shellac) – aqueous solution
• Plasticizers added to sustain stable enteric properties with Sodium Alginate
same indent for "Added plasticizers"?

Houston Smith, 3/28/2013
• Enteric coated soft-gel

• Dissolution Protocol USP 35 – NF 30 followed
  • 2040 Disintegration and Dissolution of dietary supplements
    • Simulated Gastric Testing (SGF)
      o Passes 60 minutes and 120 minutes
    • Simulated Intestinal Testing (SIF)
      o Passes disintegration in 60 minutes

• Stability of Enteric coated soft-gels
what is <2040>?
Houston Smith, 3/28/2013
**FUNCTIONAL PROPERTIES**

**SEALANT**

Ibuprofen Release Profile: Uncoated & Shellac Coated

- **Uncoated 6.8 pH**
- **Uncoated 5.5 pH**
- **3% wt gain 6.8 pH**
- **3% wt gain 5.5 pH**
- **3% wt gain 1.2 pH**

**Time (min)**

% Release vs. %

**MOISTURE BARRIER**

Permeation Results for Shellac

- **Actual Absorption**
- **Predicted Permeation**

% Moisture Absorption

Percent Weight Gain
Slide 17

Why would you only seal coat if there is little protection in the mouth and not as much protection in the stomach as Protect? Why not enteric coat?

Houston Smith, 3/28/2013

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Slide 18

I can't tell what this slide is about. I would annotate the two curves and expand the title definition.

Houston Smith, 3/28/2013
• Reference:
  • According to the Berlin College of Pharmacy,\(^5\)
    • Shellac-coated tablets showed
      • Decreased water uptake rates than HPMC-coated systems at the same coating level.
      • Increased stability of acetaminophen compared with HPMC-coated systems, irrespective of the storage humidity
        • Overall, lower shellac coating levels were required to achieve the same degree of drug protection
        • Shellac coatings effectively masked the unpleasant taste of acetaminophen tablets\(^5\)

  • According to the International Journal of Drug Testing, the normal pH range for saliva is considered to be 5.6 to 7.9. Children have higher pH, Adults average 6.5.
did you mean to switch fonts? Indention is different on "Shellac coatings"

Houston Smith, 3/28/2013
IMMEDIATE RELEASE FUNCTIONAL PROPERTIES

• Creating Immediate Release (IR)
  • Incorporate other polymers (5 to 50% w/w)
    • Hydroxypropyl methylcellulose (HPMC)
    • Methyl cellulose (MC)
    • Hydroxypropyl cellulose (HPC)
    • Polyvinyl pyrrolidone (PVP)
    • Modified starches & Maltodextrin
    • Natural gums

• Benefits
  • Increased
    • Solutions solids
    • Lower viscosity
      • Finer atomization
    • Coating uniformity
    • Production through-puts
    • Glossiness
  • Aesthetic appeal

ABOUT SHELLAC REGULATORY

• Shellac is an approved food additive:
  • US & Europe

• Shellac is listed:
  • USP & European Pharmacopoeia
  • JP, FCC, E904

• Flexible product development
• Global commercialization
• Natural coating system
use commas at the ends or don't, not both ways.

Houston Smith, 3/28/2013
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7. TONY CHUFFO, CORIEL ASSOCIATES INC: E-MAIL CORRESPONDENCE ON APRIL 1, 2013 6:20PM.

• Excipientfest 2013 Forum
• Sensient Laboratory Personnel for Product Testing
• All supporting references & correspondences