Hydroalcoholic Gel Regulation update

Hydroalcoholic gels for hand antisepsis are regulated by the European Biocide Directive. (Regulation (EU) n°528/2012). They belong to “biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.”

Ingredients that inspire

A new French decree has just been published on 20 March 2020. It allows the temporary availability on the market and use of approved hydroalcoholic formulas with new polymers by derogation.

### Hydroalcoholic Gel 1

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol absolute</td>
<td>650 to 750 ml</td>
</tr>
<tr>
<td>or 96° % v/v</td>
<td>675 to 777 ml</td>
</tr>
<tr>
<td>or 95° % v/v</td>
<td>681 to 786 ml</td>
</tr>
<tr>
<td>or 90° % v/v</td>
<td>720 to 830 ml</td>
</tr>
<tr>
<td>Glycerin</td>
<td>50 ml</td>
</tr>
<tr>
<td>Among listed thickeners: SEPINOV™ EMT 10</td>
<td>10 to 20 ml</td>
</tr>
<tr>
<td>Aqua/Water</td>
<td>Up to 1000 ml</td>
</tr>
</tbody>
</table>

### Hydroalcoholic Gel 2

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol or 96° % v/v</td>
<td>58% p/p (~ 65% v/v at 20 °C)</td>
</tr>
<tr>
<td>or 95° % v/v</td>
<td>59.1% p/p (~ 65% v/v at 20 °C)</td>
</tr>
<tr>
<td>or 90° % v/v</td>
<td>63.7% p/p (~ 65% v/v at 20 °C)</td>
</tr>
<tr>
<td>Glycerin or Propylene glycol or Butylene glycol or Propanediol or Diglycerin</td>
<td>0.5 to 5% p/p</td>
</tr>
<tr>
<td>Among listed thickeners: SEPIMAX ZEN™</td>
<td>0.4 to 0.8% p/p</td>
</tr>
<tr>
<td>or SEPINOV™ EMT 10</td>
<td>0.5 to 2% p/p</td>
</tr>
<tr>
<td>or SIMULGEL™ 600</td>
<td>1 to 4% p/p</td>
</tr>
<tr>
<td>Aqua/Water</td>
<td>Up to 100%</td>
</tr>
</tbody>
</table>

Seppic polymers make hydroalcoholic formulas easy to use with gel texture. Formulas have variable viscosities and rheological behaviour. All these indicative formulas below contain more than 60% of alcohol.

**Hydroalcoholic Gel EU06371A**
- **A** Aqua/Water Up to 100% Ethanol 95° 67.00%
- **B** SEPIGEL™ 305 3.00%
  - Turbid Gel 35,000 mPas Brookfield S456 68.37% v/v

**Hydroalcoholic blue Gel EU07037A**
- **A** Aqua/Water Up to 100% Ethanol 95° 65.00%
  - Colorant Up to SEPIPLUS™ 400 2.25%
  - Turbid Gel 45,000 mPas Brookfield S456 72.84% v/v

**Transluclid Hydro-alcoholic Gel - EU7614**
- **A** Aqua/Water Up to 100% Ethanol 95° 65.00%
  - **SEPINOV™ EMT 10** 0.80%
  - Transluclid liquid 580 mPas Brookfield S356 71.49% v/v
  - Gel texture with SEPINOV™ EMT 10 (ethanol 95° 65% w/w - 68.27% v/v) available on www.seppic.com

**Moisturizing Hydro-alcoholic Gel - AS40067A**
- **A** Aqua/Water Up to 100% Glycerin 3.00%
  - Ethanol 95° 66.00%
- **B** SEPIMAX ZEN™ 0.80%
- **C** AQUAXYL™ 1.00%
  - Transparent Gel 14,000 mPas Brookfield S356 74.4% v/v

*Equivalence in accordance with JORF Decree 20th March 2020

They allow to incorporate high levels of solvents, especially 95° of alcohol. Handling is easy with immediate thickening without neutralization, cold processable.

**SEPIGEL™ 305 (liquid)**
- Polyacrylamide - C13-14 Isoparaffin - Laureth-7
- Compatibility ethanol 95°: 70% p/p (~76.99% v/v) at 3%
- Equipment:

**SEPIPLUS™ 400 (liquid)**
- Polyacrylate 13 - Polysobutene - Polysorbate 20
- Compatibility ethanol 95°: >65% p/p (~71.49% v/v) at 2%
- Equipment:

**SEPINOV™ EMT 10 (powder)**
- Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurophosphatopolymer
- Compatibility ethano 95°: >95% p/p (~95% v/v) at 2.8%
- Equipment:

**SEPIMAX ZEN™ (powder)**
- Polyacrylate Crosspolymer
- Compatibility ethanol 95°: >95% p/p (~95% v/v) at 2.8%
- Equipment:

**Process 1:**
Gradual ethanol addition

**Process 2:**
Dilution of initial gel for easier shearing and polymer dispersion (powder grades)

- Appearance of the gel becomes more transparent with a high percentage of ethanol
- Let stand the gel for better homogenization and more transparency