COPPER

Date: November 8, 2007

Proper name(s): Copper (Sweetman 2007; O’Neil et al. 2001)

Common name(s): Copper (Sweetman 2007; O’Neil et al. 2001)

Source material(s):

- Calcium copper edetate
  (Sweetman 2007)
- Copper (II) acetate/Cupric acetate
  (O’Neil et al. 2001)
- Copper (II) bisglycinate/Cupric bisglycinate
  (Albion 2000)
- Copper (II) carbonate/Cupric carbonate
  (O’Neil et al. 2001)
- Copper (II) chloride/Cupric chloride
  (Sweetman 2007; O’Neil et al. 2001)
- Copper (II) chloride dihydrate/Cupric chloride dihydrate
  (Sweetman 2007; O’Neil et al. 2001)
- Copper (II) citrate/Cupric citrate
  (O’Neil et al. 2001)
- Copper (II) fumarate/Cupric fumarate
  (HC 2007)
- Copper (II) gluconate/Cupric gluconate
  (Sweetman 2007; IOM 2003; O’Neil et al. 2001)
- Copper (II) glutarate/Cupric glutarate
  (HC 2007)
- Copper (II) hydrolyzed animal protein (HAP) chelate/Cupric HAP chelate
  (Albion 1993)
- Copper (II) hydrolyzed vegetable protein (HVP) chelate/Cupric HVP chelate
  (Albion 1993)
- Copper (II) malate/Cupric malate
  (HC 2007)
- Copper (II) succinate/Cupric succinate
  (HC 2007)
Copper (II) sulfate/Cupric sulfate
(Sweetman 2007; IOM 2003; O’Neil et al. 2001)

Copper (II) sulfate pentahydrate/Cupric sulfate pentahydrate
(Sweetman 2007; IOM 2003; O’Neil et al. 2001)

Note: The slash (/) indicates that the terms are synonyms. Either term may be selected by the applicant.

Route(s) of administration: Oral

Dosage form(s): Those pharmaceutical dosage forms suited to oral administration, including but not limited to chewable tablets, caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons, or tablespoons are acceptable. This monograph is not intended to include food-like dosage forms such as bars, chewing gums or beverages.

Use(s) or Purpose(s): Statement(s) to the effect of:

General: A factor in the maintenance of good health (IOM 2006; IOM 2001).

Specific:
- Helps to produce and repair connective tissue (Shils et al. 2006; IOM 2001; Groff and Gropper 2000).
- Helps to form red blood cells (IOM 2006; Shils et al. 2006; IOM 2001; Groff and Gropper 2000).

Dose-specific: For products providing daily doses of copper at or above the Recommended Dietary Allowance (RDA) (adjusted for the life stage groups), the following use or purpose is acceptable:
- Helps to prevent copper deficiency (IOM 2006; Shils et al. 2006; IOM 2001; Groff and Gropper 2000).
  [Note: Copper deficiency is rare in North America (IOM 2006; Shils et al. 2006; IOM 2001; Groff and Gropper 2000).]

See Appendix 1 for definitions and Table 2 in Appendix 2 for RDA values.
Dose(s):

Table 1: Dose information for copper presented as dose per day

<table>
<thead>
<tr>
<th>Life stage group</th>
<th>Minimum Copper (µg/day)</th>
<th>Maximum Copper (µg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Children</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-3 y</td>
<td>35</td>
<td>700</td>
</tr>
<tr>
<td>4-8 y</td>
<td>35</td>
<td>2,500</td>
</tr>
<tr>
<td><strong>Adolescents</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9-13 y</td>
<td>35</td>
<td>4,000</td>
</tr>
<tr>
<td>14-18 y</td>
<td>65</td>
<td>6,500</td>
</tr>
<tr>
<td><strong>Adults</strong>¹</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ 19 y</td>
<td>65</td>
<td>8,000</td>
</tr>
</tbody>
</table>

¹ Based on approximately 5% of the highest RDA (IOM 2006). See Appendix 1 for definitions and Table 2 in Appendix 2 for RDA values.

² Maximum dose based on the Tolerable Upper Intake Level (UL) less average dietary intake (adapted from IOM 2006).

³ Includes pregnant and breastfeeding women.

Duration of use: No statement required.

Risk information: Statement(s) to the effect of:

Caution(s) and warning(s): When copper HAP or HVP chelate is used as a source material:
For an adult subpopulation only.

Contraindication(s): No statement required.

Known adverse reaction(s): No statement required.

Non-medicinal ingredients: Must be chosen from the current NHPD List of Acceptable Non-medicinal Ingredients and must meet the limitations outlined in the list.

Specifications: Must comply with the minimum specifications outlined in the current NHPD Compendium of Monographs.

References:


Appendix 1: Definitions

Recommended Dietary Allowances (RDA): The average daily dietary nutrient intake level sufficient to meet the nutrient requirements of nearly all (97-98%) healthy individuals in a particular life stage and gender group (IOM 2006).

Tolerable Upper Intake Level (UL): The highest average daily nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects may increase (IOM 2006).

Appendix 2: RDA Values

The RDA values for copper are provided below. For the purpose of this monograph, these values are intended to:
- provide targets for setting appropriate supplement dosage levels;
- provide the minimum dose for the use of the dose specific use or purpose: “Helps to prevent copper deficiency”;
- facilitate the optional labelling of % RDA values.

Table 2: Recommended Dietary Allowance for copper based on life stage group (IOM 2006)

<table>
<thead>
<tr>
<th>Life stage group</th>
<th>Copper (µg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children 1-3 y</td>
<td>340</td>
</tr>
<tr>
<td>4-8 y</td>
<td>440</td>
</tr>
<tr>
<td>Adolescents 9-13 y</td>
<td>700</td>
</tr>
<tr>
<td>14-18 y</td>
<td>890</td>
</tr>
<tr>
<td>Adults ≥ 19 y</td>
<td>900</td>
</tr>
<tr>
<td>Pregnancy 14-50 y</td>
<td>1,000</td>
</tr>
<tr>
<td>Breastfeeding</td>
<td>1,300</td>
</tr>
</tbody>
</table>