CHROMIUM

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient. It is a referenced document to be used as a labelling standard.

Note: Text in parentheses is additional optional information which can be included on the PLA and product labels at the applicants’ discretion. The solidus (/) indicates that the terms are synonyms or that the statements are synonymous. Either term or statement may be selected by the applicant.

Date: December 9, 2009

Proper name(s): Chromium (O’Neil et al. 2009; Sweetman 2007)

Common name(s): Chromium (O’Neil et al. 2009; Sweetman 2007)

Source material(s):
- Chromium (III) bisglycinate/Chromic bisglycinate (Albion 2000)
- Chromium (III) chloride/Chromic chloride (O’Neil et al. 2009)
- Chromium (III) chloride hexahydrate/Chromic chloride hexahydrate (O’Neil et al. 2009)
- Chromium (III) citrate/Chromic citrate (HC 2007)
- Chromium (III) dinicotinate/Chromic dinicotinate (Evans and Pouchnik 1993)
- Chromium (III)-enriched yeast/Chromic-enriched yeast (HC 2007)
- Chromium (III) fumarate/Chromic fumarate (HC 2007)
- Chromium (III) glutarate/Chromic glutarate (HC 2007)
- Chromium (III) hydrolyzed animal protein (HAP) chelate/Chromic HAP chelate (Albion 1995; Albion 1993)
- Chromium (III) hydrolyzed vegetable protein (HVP) chelate/Chromic HVP chelate
Chromium (III) malate/Chromic malate
(HC 2007)

Chromium (III) nicotinate/Chromic nicotinate
(Grant et al. 1997; Evans and Pouchnik 1993)

Chromium (III) picolinate/Chromic picolinate
(EFSA 2009)

Chromium (III) pidolate/Chromic pidolate
(Anderson et al. 2001)

Chromium (III) polynicotinate/Chromic polynicotinate
(Murray 1996)

Chromium (III) potassium sulfate dodecahydrate/Chromic
potassium sulfate dodecahydrate
(ANZFA 2004)

Chromium (III) succinate/Chromic succinate
(HC 2007)

Chromium (III) sulfate /Chromic sulfate
(ANZFA 2004; ANZFA 2002)

**Route(s) of administration:** Oral

**Dosage form(s):** The acceptable pharmaceutical dosage forms include, but are not limited to, chewables (e.g. gummies, tablets), caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons or tablespoons. This monograph is not intended to include foods or 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)

**Specific:**

- Provides support for healthy glucose metabolism (IOM 2006; Shils et al. 2006; IOM 2001; Groff and Gropper 2000).
- Helps the body to metabolize carbohydrates and fats (IOM 2006; Shils et al. 2006; IOM 2001; Groff and Gropper 2000).

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

See Appendix 1 for definitions and Table 2 in Appendix 2 for AI values.

**Dose(s):**

**Note:**
- When chromium picolinate is used as source material for elemental chromium, the product should be indicated for adult subpopulation only (EFSA 2009; EVM 2003; SCF 2003).
- When chromium HAP chelate or chromium HVP chelate is used as source material, the product should be indicated for an adult subpopulation only.

<table>
<thead>
<tr>
<th>Life stage group</th>
<th>Chromium III (μg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults ≥ 19 y</td>
<td>Minimum¹</td>
</tr>
<tr>
<td></td>
<td>2.2</td>
</tr>
</tbody>
</table>

¹ Based on approximately 5% of the highest AI (IOM 2006). See Appendix 1 for definitions and Table 2 in Appendix 2 for AI values.
² Maximum dose supported by the following references: Kleefsta et al. 2006; Campbell et al. 2002; Anderson et al. 2001; Campbell et al. 1999; Crawford et al. 1999; Anderson et al. 1997; Campbell et al. 1997; Roebuck et al. 1991; Mossop et al. 1983.
³ Includes pregnant and breastfeeding women, except for use of chromium picolinate (EFSA 2009; Manygoats et al. 2002; IOM 2001; Sugden et al. 1992).

**Duration(s) of use:** Statement(s) to the effect of:

For products using chromium picolinate as source material:

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

**Caution(s) and warning(s):**

For products providing 200 - 500 μg/day of elemental chromium from chromium picolinate:
Consult a health care practitioner prior to use if you have a kidney disorder (Wani et al. 2006; Cupp and Tracy 2003; Cerulli et al. 1998; McCarty 1997; Wasser et al. 1997) and/or diabetes (Bunner and McGinnis 1998).
**Contraindication(s):**

For products using chromium picolinate as source material: Do not use if you are pregnant or breastfeeding (EFSA 2009; Manygoats et al. 2002; IOM 2001; Sugden et al. 1992).

**Known adverse reaction(s):** No statement required.

**Non-medicinal ingredients:** Must be chosen from the current NHPD *Natural Health Products Ingredients Database* and must meet the limitations outlined in that database.

**Specifications:** The finished product must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs.*

**References cited:**


Evans GW, Pouchnik DJ. 1993. Composition and biological activity of chromium-pyridine


References reviewed:


Bosco MC, Rapisarda A, Massanza S, Melillo G, Young H, Varesio L. 2000. The tryptophan catabolite picolinic acid selectively induces the chemokines macrophage inflammatory protein-
1α and -1β in macrophages. The Journal of Immunology 164(6):3283-3291.


Dillon CT, Lay PA, Bonin AM, Cholewa M, Legge GJF. 2000. Permeability, cytotoxicity, and genotoxicity of Cr(III) complexes and some Cr(V) analogues in V79 Chinese hamster lung cells. Chemical Research in Toxicology 13(8):742-748.


toxicity and carcinogenicity studies of chromium picolinate monohydrate administered in feed to F344/N rats and B6C351 mice for 2 years. National Toxicology Program. Food and Chemical Toxicology 47: 729-733.


Appendix 1: Definitions

**Adequate Intake (AI):** The recommended average daily intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate. An AI is used when a Recommended Dietary Allowance (RDA) cannot be determined (IOM 2006).

**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).

Appendix 2: Adequate intake (AI) values

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

**Table 2: Adequate Intake values for chromium based on life stage group (IOM 2006)**

<table>
<thead>
<tr>
<th>Life stage group</th>
<th>Chromium (μg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult males</td>
<td></td>
</tr>
<tr>
<td>19-50 y</td>
<td>35</td>
</tr>
<tr>
<td>≥ 51 y</td>
<td>30</td>
</tr>
<tr>
<td>Adult females</td>
<td></td>
</tr>
<tr>
<td>19-50 y</td>
<td>25</td>
</tr>
<tr>
<td>≥ 51 y</td>
<td>20</td>
</tr>
<tr>
<td>Pregnancy</td>
<td></td>
</tr>
<tr>
<td>19-50 y</td>
<td>30</td>
</tr>
<tr>
<td>Breastfeeding</td>
<td></td>
</tr>
<tr>
<td>19-50 y</td>
<td>45</td>
</tr>
</tbody>
</table>