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Dear Sir/Madam

### **Consultation: Permissible ingredients annual changes 2020-2021**

CHP Australia welcomes the opportunity to provide feedback on the proposed changes.

CHP Australia is the leading voice and industry body for **manufacturers and distributors of consumer healthcare products**, which includes non-prescription medicines. We strive to advance consumer health through **responsible Self Care** and were previously known as the Australian Self Medication Industry (ASMI).

Our key priorities for the industry include **improving health literacy, growing the consumer healthcare products industry** and **increasing access to medicines** where appropriate.

#### **Feedback on Proposed Changes**

<b>Ingredient name</b>	<b>Proposed changes</b>	<b>Comments</b>
<p><b>Easily-dissociable forms of magnesium in the Therapeutic Goods (Permissible Ingredients) Determination</b></p> <ul style="list-style-type: none"> <li>• ALUMINIUM MAGNESIUM SILICATE</li> <li>• BITTERN</li> <li>• DIBASIC MAGNESIUM CITRATE TETRAHYDRATE</li> <li>• DIBASIC MAGNESIUM PHOSPHATE TRIHYDRATE</li> <li>• DRIED MAGNESIUM SULFATE</li> <li>• HEAVY MAGNESIUM OXIDE</li> </ul>	<p><b>Proposed specific requirements</b></p> <p>Magnesium is a mandatory component of this ingredient.</p> <p>When used in medicines:</p> <ol style="list-style-type: none"> <li>a. with an oral route of administration;</li> <li>b. not indicated for laxative (or related) use; and</li> <li>c. the maximum recommended daily dose for:</li> </ol>	<p>CHP Australia does not oppose the proposed dosage limits and the associated warning:</p> <ul style="list-style-type: none"> <li>• 'This product may have a laxative effect. Discontinue use if you develop diarrhoea (or words to that effect)'.</li> </ul> <p>To improve the clarity of the conditions, CHP Australia suggests that the requirements are amended to read:</p>



<ul style="list-style-type: none"> <li>• LEVOCARNITINE</li> <li>• MAGNESIUM CITRATE</li> <li>• LIGHT MAGNESIUM OXIDE</li> <li>• MAGNESIUM AMINO ACID CHELATE</li> <li>• MAGNESIUM ASCORBATE</li> <li>• MAGNESIUM ASCORBATE MONOHYDRATE</li> <li>• MAGNESIUM ASPARTATE</li> <li>• MAGNESIUM ASPARTATE DIHYDRATE</li> <li>• MAGNESIUM ASPARTATE TETRAHYDRATE</li> <li>• MAGNESIUM CARBONATE HYDRATE</li> <li>• MAGNESIUM CHLORIDE 4.5-HYDRATE</li> <li>• MAGNESIUM CHLORIDE HEXAHYDRATE</li> <li>• MAGNESIUM CITRATE</li> <li>• MAGNESIUM CITRATE NONAHYDRATE</li> <li>• MAGNESIUM CITRATE TETRADECAHYDRATE</li> <li>• MAGNESIUM DIGLUTAMATE</li> <li>• MAGNESIUM GLUCONATE</li> <li>• MAGNESIUM GLYCEROPHOSPHATE</li> <li>• MAGNESIUM GLYCINATE</li> <li>• MAGNESIUM GLYCINATE DIHYDRATE</li> <li>• MAGNESIUM HYDROGEN PHOSPHATE</li> <li>• MAGNESIUM HYDROXIDE</li> <li>• MAGNESIUM LYSINATE</li> <li>• MAGNESIUM METHIONINATE</li> <li>• MAGNESIUM OROTATE</li> <li>• MAGNESIUM OROTATE DIHYDRATE</li> <li>• MAGNESIUM OXIDE</li> <li>• MAGNESIUM PHOSPHATE PENTAHYDRATE</li> <li>• MAGNESIUM PHOSPHATE TRIBASIC</li> </ul>	<p>i. children aged between 1 and 3 years (inclusive) provides 65 mg or more total magnesium;</p> <p>ii. children aged between 4 and 8 years (inclusive) provides 110 mg or more total magnesium; or</p> <p>iii. individuals aged 9 years or older provides 250 mg or more total magnesium;</p> <p>the following warning statements are required on the label:</p> <ul style="list-style-type: none"> <li>• 'This product may have a laxative effect. Discontinue use if you develop diarrhoea (or words to that effect)'.</li> </ul> <p>When used in medicines with an oral route of administration, the following warning statement is required on the label:</p> <ul style="list-style-type: none"> <li>• 'Not suitable for infants under the age of twelve months' (or words to that effect).'</li> </ul>	<p>c. <b>where</b> the maximum recommended daily dose for</p> <p>CHP Australia suggests that the warning statement for medicines with an oral route of administration is amended to:</p> <ul style="list-style-type: none"> <li>• <b>'Adults only' Or</b> 'Not suitable for infants under the age of twelve months' (or words to that effect).</li> </ul> <p>This will minimise the impact on labelling for products that are not intended to be used in children (e.g. products that also contain borax for bone health).</p>
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- MAGNESIUM PYRUVATE
  - MAGNESIUM STEARATE
  - MAGNESIUM SULFATE DIHYDRATE
  - MAGNESIUM SULFATE HEPTAHYDRATE
  - MAGNESIUM SULFATE MONOHYDRATE
  - MAGNESIUM SULFATE TRIHYDRATE
  - MAGNESIUM TRISILICATE

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**ANDROGRAPHIS  
PANICULATA**

**Additional warning statement  
on the label:**

- (ANDROT)  
Andrographis may cause taste disturbance including loss of taste. If you develop any adverse symptoms, stop use and seek medical advice (or words to that effect).

CHP Australia does not oppose the proposed additional warning for products containing *Andrographis paniculata*.

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CHP Australia is available for any further information requests or consultation on these matters.

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