Low inorganic arsenic in hydrolysed-rice formula used for cow's milk protein allergy


Published in:
Pediatric allergy and immunology : official publication of the European Society of Pediatric Allergy and Immunology

Document Version:
Peer reviewed version

Queen's University Belfast - Research Portal:
Link to publication record in Queen's University Belfast Research Portal

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We analysed dry formula powder rather than reconstituted formula, to eliminate confounding due to arsenic present in household water. Levels of inorganic arsenic in all the HRF samples tested were very low, and similar to that reported by Vela et al. for conventional cow’s milk infant formula but slightly higher than that reported by Jackson et al. using a different analysis platform. The average volume of consumption of hypoallergenic formula at 0-6 months is 600-800 ml per day, which would require 90-120g of powder (based on an average scoop size of 4.5g for HRF). This would equate to 1.3-1.8 µg of As(V), which in an 8 kg infant (50th centile for weight, z score 0) is an exposure of 0.16-0.23 µg/kg body weight (b.w.). This is well below the average exposure in childhood generated from data produced by European Food Safety Authority (EFSA) for both infants [0.24 ug/kg – 0.43 ug/kg b.w./per day] and toddlers [0.32-0.45 ug/kg per b.w./day]. The As(V) exposure based on an average infant would also be 10-fold less than the limit for exposure set by the World Health Organisation at 2ug/kg per b.w./day. It is important to note that all these studies are based on analysis of formula powder; actual As(V) exposure is significantly influenced by the arsenic in the tap water used to reconstitute the formula, which (according to EFSA) is 1.1-2.0 µg/kg b.w. There is no maximum level set by EFSA for infant formulas currently, but water for human consumption is set at 10 ug/L (Council Directive 98/83/EC).

Table 1: Summary of hydrolysed rice formulas analysed in this study and results of arsenic content

<table>
<thead>
<tr>
<th>Name of feed</th>
<th>Origin</th>
<th>Characteristic</th>
<th>As(V)* (ug/kg)</th>
<th>DMA 0 (ug/kg)</th>
<th>Sum of Species [As(V)+DMA] (ug/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modilac Expert Riz 1 (batch one)</td>
<td>France</td>
<td>Hydrolysed rice suitable from 0-6 months</td>
<td>9</td>
<td>2</td>
<td>11</td>
</tr>
<tr>
<td>Modilac Expert Riz 1 (batch 2)</td>
<td>France</td>
<td>Hydrolysed rice suitable from 0-6 months</td>
<td>20</td>
<td>15</td>
<td>35</td>
</tr>
<tr>
<td>Modilac Expert Riz 2 (batch 1)</td>
<td>France</td>
<td>Hydrolysed rice suitable from 6-12 months</td>
<td>12</td>
<td>13</td>
<td>25</td>
</tr>
<tr>
<td>Modilac Expert Riz 2 (batch 2)</td>
<td>France</td>
<td>Hydrolysed rice suitable from 6-12 months</td>
<td>13</td>
<td>14</td>
<td>27</td>
</tr>
<tr>
<td>Modilac Expert Riz AR 1 (batch 1)</td>
<td>France</td>
<td>Hydrolysed rice suitable from 0-6 months thickened with carob and corn starch</td>
<td>14</td>
<td>19</td>
<td>33</td>
</tr>
<tr>
<td>Product</td>
<td>Country</td>
<td>Description</td>
<td>As(V)</td>
<td>DMA</td>
<td>LOD (mg/kg)</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>-------</td>
<td>-----</td>
<td>-------------</td>
</tr>
<tr>
<td>Modilac Expert Riz AR 2 (batch 2)</td>
<td>France</td>
<td>Hydrolysed rice suitable from 6-12 months thickened with carob and corn starch</td>
<td>12</td>
<td>6</td>
<td>18</td>
</tr>
<tr>
<td>Novalac Novarice (batch 1)</td>
<td>Belgium and France</td>
<td>Extensively hydrolysed rice from 0-12 months</td>
<td>11</td>
<td>3</td>
<td>13</td>
</tr>
<tr>
<td>Novalac Novarice (batch 2)</td>
<td>Belgium and France</td>
<td>Extensively hydrolysed rice from 0-12 months</td>
<td>11</td>
<td>3</td>
<td>13</td>
</tr>
<tr>
<td>Plasmon Risolac (batch 1)</td>
<td>Italy</td>
<td>Hydrolysed rice suitable from 0-12 months</td>
<td>9</td>
<td>6</td>
<td>15</td>
</tr>
<tr>
<td>Plasmon Risolac (batch 2)</td>
<td>Italy</td>
<td>Hydrolysed rice suitable from 0-12 months</td>
<td>10</td>
<td>5</td>
<td>15</td>
</tr>
</tbody>
</table>

*As(V) = inorganic arsenic
◊DMA = dimethylarsinic acid

The limit of detection (LOD) for all species by HPLC-ICP-MS (calculated from DMA calibration) were 0.0003 mg/kg.

The main limitation of this study was that samples were not compared to extensively hydrolysed or amino acid formula, which are the mainstay of treatment formulas for CMPA. However, the latter have been used for the last 60 years in the treatment of CMPA and were assumed safe. In the light of current data, a future study establishing As(V) levels also in these formulas would be recommended.

In conclusion, this study found that As(V) levels in hydrolysed rice formulas are well within the safe range as stipulated by EFSA/WHO. However, it is important take the source of water into account when mixing formulas, which may affect levels.
References


Authors

Rosan Meyer, Imperial College, London W2 1NY, UK and corresponding author – r.meyer@imperial.ac.uk

Manus P Carey, Institute for Global Food Security, Queen’s University Belfast, David Keir Bld, Malone Rd, Belfast, BT5 5BN, Northern Ireland

Paul Turner, Imperial College, London W2 1NY, UK

Andrew. A. Meharg, Institute for Global Food Security, Queen’s University Belfast, David Keir Bld, Malone Rd, Belfast, BT5 5BN, Northern Ireland

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Contribution of Authors

RM write up of manuscript and sourcing of rice formulas in Europe used for cow’s milk protein allergy

MC laboratory analysis and review of manuscript

PT critical review of manuscript

AM critical review of manuscript and direction of methodology of the study

Conflict of Interest

None of the authors declare any conflict of interest pertaining the current publication

Source of funding

No funding was required for this study