



January 01, 2021

GRAS Status – Rice Concentrate (Rice Hulls)

To Whom It May Concern:

In 2007 RIBUS commercially introduced a new ingredient into the marketplace with the label declaration of “Rice Concentrate” or “Rice Hulls”. This ingredient went through a process of review and was deemed to be GRAS on a self- determination basis.

To further elaborate on the product, it was originally introduced as “Certified Organic” and later expanded to the status of natural (for companies that did not desire organic ingredients). The product is 100% rice hulls. The hulls are steam sterilized for microbial control, followed by particle size reduction and packaging. Nothing is added and nothing is taken away. The product is produced in a food grade facility and Good Manufacturing Practices (GMP’s) are followed.

RIBUS convened a panel of internationally recognized experts (“Expert Panel”), qualified by their scientific training and experience to evaluate the safety of food and food ingredients, to critically evaluate the available information on ground rice hulls and determine the Generally Recognized as Safe (GRAS) status of the proposed uses of RIBUS’ ground rice hulls for consumption by humans or livestock (food – bakery, beverages, confection, prepared foods, etc. / feed, dietary supplements, personal care and skin care). The Expert Panel, individually and then collectively, critically evaluated the materials prepared by RIBUS and other materials deemed appropriate including method of manufacture and product specifications, batch analyses, intended conditions of use, estimated exposure from the proposed uses and a critical assessment of the scientific literature on the safety of ground rice hulls and other dietary fibers.

Following its independent critical evaluation of this information, the Expert Panel convened and unanimously concluded that the proposed uses of RIBUS’ ground rice hulls, manufactured consistent with current Good Manufacturing Practice (cGMP), are safe and GRAS based on scientific procedures and through experience based on common use in foods in accordance with section 201(s) (21 U. S. C. §321 (s)) of the Federal Food, Drug, and Cosmetic Act (21U. S. C. §301 et. seq.) set forth at 21 CFR 170. 30.

It is the opinion of the Expert Panel that other qualified experts would concur with this conclusion.

<p>Robert J. Nicolosi, Ph.D. Professor Emeritus Department of Clinical Laboratory & Nutritional Sciences University of Massachusetts- Lowell (Lowell, MA)</p>	<p>Michael W. Pariza, Ph. D. Professor Emeritus Food Science Director Emeritus Food Research Institute University of Wisconsin-Madison (Madison, WI)</p>
<p>Joseph F. Borzelleca, Ph.D. Professor Emeritus Department of Pharmacology & Toxicology VCU School of Medicine (Richmond, VA)</p>	

We have customers across North America, Europe and other regions of the world using the Rice Concentrate ingredients. Should you have any further questions or need additional information, please let us know.

Best regards,

Karen Hansen
Regulatory / Documents Manager