



Christoph H. Röhrig, Ph.D.  
Glycom A/S  
Kogle Allé 4  
2970 Hørsholm  
DENMARK

Re: GRAS Notice No. GRN 000815

Dear Dr. Röhrig:

We are issuing a revised copy of the response letter for GRN 000815. The original letter for this GRAS notice was signed on August 20, 2019. In an email dated January 15, 2020, Dr. Marta H. Miks of Glycom A/S (Glycom) informed us of an omission in the discussion of the ingredient specifications in our letter. In her email, Dr. Miks also informed us that the exposure estimates for the notified ingredient in infants were incorrectly reported in the notice. In an email dated February 5, 2020, we requested that Glycom submit a supplement stating the correct exposure estimates and discussing any related impact on the safety conclusion described in the notice. Glycom submitted a supplement on March 26, 2020. In response to the information about our omission, we are including the specification for lactose on page 2, paragraph 3 of our letter. In response to the supplement, we are correcting errors in the exposure estimates for the notified ingredient in infants on page 3, paragraph 1 of our letter. In a new footnote on page 4 of our letter, we include your statement that the corrected exposure estimates do not change your safety conclusion.

We regret any inconvenience that our error may have caused, and we appreciate your supplement correcting the errors in your GRAS notice. If you have any questions, please contact me by electronic mail at [Shayla.WestBarnette@fda.hhs.gov](mailto:Shayla.WestBarnette@fda.hhs.gov) or by telephone at 240-402-1262.

Sincerely,

Shayla West-  
barnette -S

Digitally signed by Shayla  
West-barnette -S  
Date: 2020.05.07 11:09:41  
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Shayla West-Barnette, Ph.D.  
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