alphagary

orbia Polymer Solutions

September 12, 2025

Mr. Bob Burton
Nexeo Plastics
rburton@nexeoplastics.com

Dear Bob:

In response to your request, this letter provides EU REACH SVHC and latex information for the following product.

Nexeo Plastics (Customer ID # 4510001569)			
Product	Nexeo P/N	AG P/N	Previous P/N
ALPHAMED 2222C-68 Clear 0003	28209	5020005362	956176

EU REACH SVHC

REACH (***REGULATION (EC) No 1907/2006***) Article 56 requires any substance identified in Annex XIV to have **A**uthorization by the European Chemicals Agency, for use in the EU beyond its designated sunset date. There are 59 substances on the authorization list, and all 59 are past their respective sunset dates. Article 57 sets forth the requirements for the candidate list of substances subject to authorization in Annex XIV. These candidates are known as **Substances of Very High Concern** (SVHC) and as of 6/25/25, they number 250 substances with the addition of Reactive Brown 51 and two vPvB siloxanes. With the 0.1% (1000-ppm) regulatory threshold under REACH, the following SVHCs are declared for this product.

Bis(2-ethylhexyl) phthalate, DEHP, CAS # 117-81-7, EC # 204-211-0		
●	37-38% by weight	
●	On the SVHC list for the following properties:	
	◊	Toxic for reproduction – Article 57(c)
	◊	Endocrine disrupting properties – Article 57(f) – environment
	◊	Endocrine disrupting properties – Article 57(f) – human health
●	Annex XIV – Authorization list	
	◊	Listed, sunset date 2/21/15

Tris(4-nonylphenyl, branched and linear) phosphite, TNPP, CAS # 26523-78-4, EC # 247-759-6		
●	0.4-0.5% by weight	
●	On the SVHC list for the following properties:	
	◊	Endocrine disrupting properties – Article 57(f) - environment
●	Annex XIV – Authorization list	
	◊	Not Listed

No other declarable SVHCs > 0.1% are present in this product.

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Latex

The U.S. Food and Drug Administration released a non-binding document titled "*Recommendations for Labeling Medical Products to Inform users that the Product or Product Container is not Made with Natural Rubber Latex*" issued on December 2, 2014. In accordance with that document, we are issuing the following latex statement as recommended in the guidance for the product above:

This product is not made with natural rubber latex.

In addition, please note that we do not use latex as an ancillary material in our manufacturing process and to the best of our knowledge, our packaging materials are not made with natural rubber latex. Therefore, our product does not trigger any labeling of medical devices for natural rubber as per the instructions in 21 CFR 801.37.

Sincerely,

Troy E Brantley

Troy E. Brantley
Manager of Regulatory Compliance

Cc: Ms. Joyce Jones | Orbia PS (Alphagary)
Mr. Marco Interlandi | Orbia PS (Alphagary)
Ms. Daniela McIlwain | Orbia PS (Alphagary)