

REACH and CA Proposition 65 Assessment

From

Brittany Crocco
 Director of Quality, Avitide LLC, a Repligen Company

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Introduction

This memo intends to summarize the regulatory assessment activities for the following criteria for AVIPure® – AAV Affinity Resins.

Table 1: AVIPure® – AAV Affinity Resin regulatory assessments

Assessment	Acceptance criteria
REACH	Product must be REACH compliant and registered if applicable
Prop 65	Product must be Prop-65 compliant and registered if applicable

REACH

The AVIPure® – AAV Affinity Resins (AVIPure® – AAV2, AVIPure® – AAV8, and AVIPure® – AAV9) are comprised of two components: the custom affinity ligand and an agarose resin bead. The affinity ligand for each product is exempted from the registration requirements due to production volumes not exceeding one metric ton. The resin bead is exempt from registration due to its polymer classification. The vendor has confirmed the monomers have been registered by the appropriate suppliers; see attachment 1.

The dry weight of each AVIPure® – AAV Affinity Resin product is not projected to exceed one metric ton annually, so the final resin product is also exempt from registration.

No substances of very high concern are expected to be present in the final AVIPure® – AAV Affinity Resin products at levels that exceed the established limits. Dimethylformamide (DMF) is used early in the production process. Extensive washing of the resin in subsequent steps removes DMF to calculated levels of < 0.5 ppm.

REACH compliance assessment is ongoing with Assent Compliance.

Proposition 65

The California Proposition 65 assessment has been initiated and is in process with Intertek per quote Qu-01234593-0.

Conclusion

Compliance assessments are in process. Although the assessments are still ongoing, it has been determined that REACH registration is not required.

Attachments

Attachment 1 - General Statement of Compliance with REACH (Purolite)



Purolite[®]

Mark Price
Corporate QA & Regulatory
Affairs Manager
Llantrisant Business Park,
Llantrisant, South Wales.
CF72 8LF, UK
Telephone +44 1443 229 334
Mobile +44 7824 553 419
mark.price@purolite.com

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Statement of Compliance with REACH

Classification of Ion Exchange Resins and Synthetic Adsorbents

Under REACH, ion exchange resins and polymeric adsorbents are considered “polymers” (ref. Title I, Article 3.5) and “polymers” are exempt from Title II - Registration and Title VI - Evaluation (ref. Title I, Article 2.9). However, monomers and reactants used in their manufacture are subject to registration.

Registration of Monomers and Reactants for Purolite Ion Exchange Resins Manufactured in Europe

All monomers and reactants used in the manufacture of Purolite ion exchange resins and adsorbents are purchased only from REACH compliant suppliers. This means that all monomers and reactants were pre-registered prior to the closure date of December 1st, 2008 and full registration is now complete.

Registration of Monomers and Reactants for Purolite Ion Exchange Resins Imported into Europe

, Llantrisant, U.K, has been formally appointed the “Only Representative” application and the implementation of REACH for all Purolite products imported into the EU. Purolite Ltd., acting as the O.R., successfully pre-registered all REACH relevant substances (monomers and reactants over 2% w/w) in the imported polymers and ensured that the same substances were fully registered by the relevant deadlines.

Brexit Update

In order to prepare for any eventuality resulting from the Brexit situation, Purolite, supported by our long-term consultants, are in the process of transferring all current registrations to our Purolite S.R.L site located in Romania (Str. Aleea Uzinei, Nr. 11,505 700, Victoria, Jud. Brasov, Romania. This move will ensure there is no disruption in supply of Purolite products and we are fully compliant with EU requirements.

Substances of Very High Concern

Purolite ion exchange resins and synthetic adsorbents have SVHC’s concentration limits below the legal limits for substances of Very High Concern and are compliant with the Candidate List of the Substances of Very High Concern. The candidate list can be found at <http://echa.europa.eu/candidate-list-table>

Mark Price

Corporate QA & Regulatory Affairs Manager

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