

Product Solution

Engineering Services Group

Product Description:

Toxicological/FDA Review of 26 existing and new Asaclean (Asahi Kasei Asaclean Americas) Purging Compounds

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Scope

At the request of the client, a manufacturer of purging compounds used in the plastic food grade container molding process, submitted their proprietary ingredient lists of twenty-six (26) of their existing and new purging compounds to have a Toxicological Assessment conducted. The Toxicological Risk Assessment addressed each of these purging compounds and their ingredients as they comply with US FDA 21 CFR for items in contact with food. A Board Certified Toxicologist conducted the Toxicological Assessment.

Executive Summary

As a result of the review of the ingredient lists for all twenty-six (26) purging compounds Grades E (new), EX (new), U, UP (USA), C, CP, HP, SX, PX, NH, NF, NCR, NCT, NCF, NCH, PF, PX2, YG, SA, SL, UF2, Asaclean Plus, new UP (Japan), NB, NC, and NL.

BVCPS's Board Certified Toxicologist's opinion is as follows:

For these twenty-six (26) ASACLEAN formulations compound the review of the ingredients demonstrated that the corresponding indirect additive approvals are listed in the CFR or, if not covered directly, are similar in structure to other approved polymers or approved in a different context. Overall, it can therefore be concluded that the FDA would have no concerns with the use of these twenty-six (26) purging compounds.

Methods/Evaluation

A Board Certified Toxicologist at a BVCPS-approved Toxicological Laboratory conducted the Toxicological Assessment on the purging compounds.

The information in this report is reported as **DATA ONLY**.

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