APPLICATION NOTE
#G001-0

SiliaSphere™ SiliaFlash®

Using Silica-Based Products for Food and Drug Applications

Silicon dioxide (SiO_2) is the most abundant mineral in the Earth's crust and is considered as a non-toxic substance. It is also classified as a "***Generally Recognized as Safe (GRAS)***" substance by the U.S. Food and Drug Administration (**FDA**) when used in accordance with the "***Code of Federal Regulations Title 21 (21 CFR)***".

Silicon dioxide is nominally 99.5% synthetic amorphous silica, which may be additionally referenced as silica, silica gel, silica xerogel, or silica aerogel; therefore SiliCycle silica gel products are considered as **GRAS** under **FDA** regulations and meet their requirements for direct and indirect contact with food and drugs (*covered by 21 CFR 182.1711, 21 CFR 182.90, and 21 CFR 582.1711*).

If you need more information about "*Code of Federal Regulations Title 21 (21 CFR)*", please visit: https://www.fda.gov/drugs/development-approval-process-drugs

Functionalized Silica Gels and Consumable Products

SiliaBond® & SiliaMetS® Functionalized Silica Gels, SiliaPrep™ & SiliaSep™ Cartridges and SiliaChrom® HPLC Columns can be safely used for food and drugs applications. Below is the answer of the "*Division of Drug Information*" in the FDA's "*Center for Drug Evaluation and Research (CDER)*" regarding the use of silica-based products during food and drug synthesis:

"*Please note that the FDA does not review or approve individual components or ingredients. We evaluate and/or approve the "whole" finished product (i.e., tablet, capsule, injectable, etc) under a New Drug Application (NDA), Abbreviated New Drug Application (ANDA) and Biological Licensed Application (BLA) through the drug approval application process not reagents and/or purification methods used during the drug synthesis*."

For more information: https://www.fda.gov/drugs/development-approval-process-drugs

If you would like to get a better understanding of the drug review process, we suggest that you review the publication "*From Test Tube to Patient: Protecting America's Health Through Human Drugs*" produce by the FDA at: https://www.worldcat.org/title/from-test-tube-to-patient-protecting-americas-health-through-human-drugs/oclc/1037949046

For more information on CDER refer to the Manual of Policies and Procedures (CDER) at: https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-manual-policies-procedures-mapp

Please note that Safety Data Sheets (SDS) of each SiliCycle product are available upon request or downloadable directly on SiliCycle website in the "*Documentation*" section.

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