

Chromatography Gels

General Certification on Product Properties, Regulatory and Environmental Aspects

This Certification Data Sheet covers the following product groups which are manufactured by the ZEOCHEM group.

ZEOprep	– irregular, amorphous silica gel
ZEOprep	– irregular, amorphous silica gel, surface modified
ZEObeads	– silica gel micro beads
ZEOSphere	– spherical silica gel
ZEOSphere	– spherical silica gel, surface modified

IDENTIFICATIONS

The products that belong to one of the above product groups (“products” in the further text) are identified and registered as follows:

CAS-No.: 7631-86-9

EINECS-No.: 231-545-4

REACH-No.: 01-2119379499-16-0299

Customs tariff number: 2811.22

CHEMICAL INVENTORIES

All products comply with the following chemical inventories:

- United States: Toxic substances control Act Inventory (TSCA)
- Canada: Domestic substances List (DSL)
- Europe: European Inventory of Existing Chemical Substances (EINECS)
- Australia: Australian Inventory of Chemical Substances (AICS)
- Korea: Korean Existing Chemicals List (KECL)
- Japan: Japanese Existing and New Chemical Substances Inventory (ENCS)

MANUFACTURING

The manufacturing sites of the products are ISO 9001:2015 certified.

The manufacturing process of the silica gel does not use solvents, materials of biological origin or metal catalysts. The surface modification process of the products with such a modification may involve solvents that are removed from the final product.

No “conflict minerals” are used (tungsten, tin, tantalum or gold) in manufacturing.

SAFETY

No product is a hazardous substance with respect to storage (according to GHS) and transportation (according to IMO, ARD and IATA). All products are:

- non-toxic, non-carcinogenic, non-mutagenic, non-teratogenic
- free from hazardous substances as according to the next article
- not combustible nor explosive
- non-flammable if not surface modified
- possibly flammable if surface modified

Silica gel is considered a nano material due to its porous structure. As a member of the Association of Synthetic Amorphous Silica Producers (ASASP), Zeochem refers to the ASASP statement on engineered nanomaterials for safety considerations of silica gel as a nano material (www.asasp.eu).

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PURITY

No hazardous chemical impurities

The products are free from heavy metals (lead, mercury, cadmium, chromium) and poly-brominated aromatic compounds. They fully comply with the European Union Directive on Restriction Use of certain Hazardous Substances (RoHS) EU Directive 2011/65/EC.

No hazardous biological contaminants

The silica gel of all products is manufactured of inorganic chemicals. The surface treated products are modified with organic chemicals, but none are of biological origin. Thus, all products are free from TSE agents (Transmissible Spongiform Encephalopathy agents), biological allergens, biological toxins and GMOs (Genetically Modified Organisms).

All products do not contain "Specific Risk Materials" as defined in Annex XI, Section A, to EC Regulation 999/200/EC and do not fall under Regulation 1830/2003/EC on the traceability of GMO and Regulation 65/2004 EC on identifiers for genetically modified organisms.

Organic Compounds

Unmodified products are produced from inorganic chemicals only and therefore do not contain any organic compounds. They are free of volatile organic compounds (VOC). They also do not contain dimethyl fumarate (Commission Decision 2009/251/EC).

Only the surface modified products (such as C18, C8, CN, Diol, SH, NH₂, NH₂P and Phenyl) contain covalently bound organic compounds as indicated in the respective product specification.

During manufacturing, all solvents are removed and recycled, the surface modified products are also free of VOC or dimethyl fumarate.

Asbestos and Melamine Resins

The manufacturing of the products is conducted in an asbestos-free site. Melamine is not used on the manufacturing site for any purpose. All products are therefore free from these substances.

Elemental impurities

The silica gel of all products fully complies with limits on elemental impurities as defined in the ICH Guidelines Q3D (Step 4 version issued 16.12.2014) and BfR LII Füllstoffe (issued 01.09.2017).

USE

Goods processed with Zeochem's products should only be temporarily in contact with these products.

The concerned products are not intended as additives to food, feed, nutraceuticals, pharmaceuticals or APIs and are not intended to be taken up by humans or animals in any form. The silica gel complies with Regulation (EC) no. 1935/2004, based on article 3 of the regulation and the fact that silica gel is an approved food additive with the designation E551. Zeochem's products may therefore be used in contact with food.

Silicium dioxide, i.e. silica gel, is an approved additive to plastics that come in contact with food, as silicium dioxide is favourably listed with the identification number 504 in Regulation (EU) no. 10/2011.

ENVIRONMENT

Preservation of Natural Resources

The silica gel production process has been optimized to be energy efficient to minimize the use of natural resources.

Disposal

The waste code for unused products in the EU is 06 06 99 (Commission Decision 2014/955/EU), in Switzerland it is 06 08 99 (www.veva-online.admin.ch; VeVA, SR 814.610). Unused products should be disposed of accordingly while following the relevant local legislation.

The disposal of used products depends on the quantity and nature of residuals present in the silica gel after its use. The appropriate disposal strategy thus depends on the nature of the contamination and must take place according to the respective legislation in place.

DISCLAIMER

The information provided by this document is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for the use of the material concerned and does not liberate from own scrutiny and legal observance.