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Re: **Zochem's Zinc Oxide Food and Food Contact, FDA & other authority approvals**

The attached covers and food and food contact regulatory status for Zochem's zinc oxide.

Please contact your commercial representative, customer service, or the Zochem technical department representative(s) below for any further questions.

Regards,

John J. Stourac

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USA. Zochem U.S.A. is registered with the FDA and Department of Homeland Security as a Food Manufacturing Facility, registration/Bioterrorism Act number 17825648794.

Zochem's zinc oxide substance CAS 1314-13-2 EC/EINECS 215-222-5 is listed by the USFDA as GRAS (Generally Recognized As Safe) at 21CFR182.8991 and is USFDA approved for use wherever the use of a GRAS substance is authorized including:

- a. 21CFR §175.105(c)(1) in adhesives
- b. 21CFR §175.300(b)(2) food contact in food can liner and coatings
- c. 21CFR §175.320(a)(1) Resinous and polymeric coatings
- d. 21CFR §176.170(a)(1) paper in contact with aqueous foods
- e. 21CFR §176.180(b)(1) paper in contact with dry foods
- f. 21CFR §177.2600(c)(1) food contact in rubber articles
- g. 21CFR §177.1010(a) and §177.1010(b)(1) food contact in plastics
- h. 21CFR §582 in animal drugs, feeds, nutrient products and/or dietary supplements
- i. wherever the use of a GRAS substance is authorized.

Cereal maximum usage level 2-11 mg/day of zinc (NIH) ppm.

Canada. Zochem Canada is also FDA and Department of Homeland Security as a Food Manufacturing Facility, registration/Bioterrorism Act number 18528297564. Both Zochem Canada and Zochem U.S.A. have received a Letter of No Objection from Canada for use of our zinc oxide as an ingredient in materials with direct food contact.

EU. Zinc oxide (ZnO) is approved for use in the EU for food contact pursuant to listing in Annex I of the Commission Regulation (EU) No 10/2011, provided that plastic materials and articles shall not exceed the specific migration limit (SML) of 5 mg/kg as zinc (Zn) (Annex II). ZnO is not FRF, dual use, aromatic amines, or genotoxic. ZnO is compliant with EC No. 1935/2004 regarding materials in articles intending to come into contact with food, and GMP compliant with EC 2023/2006. Zinc oxide is also listed as approved on Germany's BfR food contact list.

China. Zinc oxide complies with P.R.C. law GB 9685-2016 Hygienic Standard for Uses of Additives in food containers and packaging materials and is on the MoH (Ministry of Health) Positive List for Additives, provided that the materials and articles contacting food do not exceed the special migration limit (SML) of 25 mg/kg as zinc (Zn), and further provided metal impurity in the ZnO does not exceed 0.01% Pb and 0.01% Cd. All Zochem's 100 and 800 grade series zinc oxide substance comply with GB 9685-2016.

Japan. Zinc oxide is also listed on MHLW's (Japanese Ministry of Health, Labor and Welfare) approved food contact substances list and Zochem is in compliance with MHLW. Zinc oxide is listed on JHOSPA's (Japan Hygienic Olefin and Styrene Plastics Association) PL (positive list) approved for food contact in plastics, provided the ZnO impurity content does not exceed 0.01% and 0.01% Cd. All of Zochem's 100 and 800 grade series zinc oxide substance meet JHOSPA limits.

Mercosur. Zinc oxide is listed on Mercosur's Positive List (RD 39/19 Table 1), and approved as an additive in plastic material and polymeric coatings intended for contact with food, with specific migration limit (LME) of 5 mg/kg as zinc (Art. 4.2.9).

Food Grade (FG). This certifies Zinc Oxide as FG (Food Grade) for incidental migration during its use in GRAS (Generally Recognized As Safe) uses.