

EPA REGISTRATION DIVISION COMPANY NOTICE OF FILING FOR PESTICIDE PETITIONS PUBLISHED IN THE FEDERAL REGISTER

**EPA Registration Division contact: Kerry Leifer, Chemistry, Inerts and Toxicology
Assessment Branch, Leifer.Kerry@epa.gov**

Evonik Corporation

Petition Number: IN-11409

EPA has received a pesticide petition IN-11409 from Evonik Corporation, 299 Jefferson Road, Parsippany, NJ 07054 requesting, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend

1. to establish an exemption from the requirement of a tolerance to include this in 40 CFR 180.910 and 40 CFR 180.950 for

[Silane, hexadecyltrimethoxy-, hydrolysis products with silica, CAS-RN: 199876-45-4] in or on the raw agricultural commodity [NA-Remove] at [NA-Remove] parts per million (ppm). EPA has determined that the petition contains data or information regarding the elements set forth in section 408 (d)(2) of FDDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* NA-Remove
2. *Analytical method.* NA-Remove
3. *Magnitude of residues.* NA-Remove

B. Toxicological Profile

1. *Acute toxicity.* The Acute Oral Toxicity Study in Rats (MRID# 51067001 indicated that the substance did not induce toxic effect in the rat following an oral administration of a single dose level of 5000 mg/kg. No mortality occurred.

The Acute Eye Irritation Study in Rabbits (MRID # 51067101) recorded slight chemosis and slight/moderate redness and discharge of the conjunctivae, shortly reversible (by 24 hours) in the animals following exposure to the substance.

The Acute Dermal Irritation Study in Rabbits (MRDI# 51067201) indicated that the

substance has no irritant effect on the skin of the rabbit following a 4 hour dermal exposure period.

The delayed Dermal Sensitization Study in Guinea Pigs (MRID#301) at 20% concentration, indicated that the substance did not elicit a sensitization response in the guinea pig, being there is no reaction observed at challenge.]

2. *Genotoxicity*. NA-Remove.
3. *Reproductive and developmental toxicity*. NA-Remove.
4. *Subchronic toxicity*. NA-Remove.
5. *Chronic toxicity*. NA-Remove.
6. *Animal metabolism*. NA-Remove
7. *Metabolite toxicology*. NA-Remove
8. *Endocrine disruption*. NA-Remove.

C. Aggregate Exposure

1. *Dietary exposure*. NA-Remove
 - i. *Food*. NA-Remove
 - ii. *Drinking water*. NA-Remove
2. *Non-dietary exposure*. NA-Remove

D. Cumulative Effects

NA-Remove

E. Safety Determination

1. *U.S. population*. NA-Remove
2. *Infants and children*. NA-Remove.

F. International Tolerances

EUROPE: Regulation (EC) 1223/2009; INCI CosIng: Silica Cetyl Silylate; Purity criteria of E551 are met. Production only on special request according to HACCP/hygienic conditions of regulations (EU) 852/2004.

CoE Resolution AP 2002 (1), paper and boards, V4 – 12.-2.2009; Ref.-No.: 86000 –

Silicic acid, silylated, Ref-No. 86285 – Silicon dioxide, silanated; A. List 1 of Additives.

CoE Resolution AP 2004(1), coatings, V3-12.02.2009; Ref.-No.: 86000 – Silicic acid, silylated, Ref-No. 86285 – Silicon dioxide, silanated; C. List 1 of Additives

CoE Resolution AP 2004(4) rubber products, V1-10.06.2004; Ref.-No.: 86000 – Silicic acid, silanated, Appendix 1 – Index list of additives.

CoE Resolution AP 2004(5), silicones, V1-10.06.2004; Ref.-No.: 86000 – Silicic acid, silanated; List 1 – No. 3 Additives.

CoE Resolution AP 2005(2), packaging inks, 21 December 2006; Ref-No. 86285 – Silicon dioxide, silanated; List 1 of Additives.

Regulation (EU) 10/2011; FCM Substance No. 87; Ref-No. 86285 – Silicon dioxide, silanated; Annex 1, Substances.

GERMANY: BfR recommendations: XV, XXI, LII; Silicic acid, also in silylated form; Purity criteria according to BfR recommendation LII are met.

Guideline for the Hygienic Assessment of Organic Coatings in Contact with Drinking Water; Ref.-No.: 86000 – Silicic acid, silanated; Annex 1: Positive list for coatings in drinking water; 1.5 Additives and accessory agents.

Water, Drinking Water and Water Protection – Rubber materials; Ref.-No.: 86000 – Silicic acid, silanated; List 1.1.2 Fillers (Purity requirements according to BfR LII.Fillers).

SWITZERLAND: Switzerland – SR 817.023.21 – Annex 10- Additives for printing inks Table 1 – List of Additives; Ref.-No.: 86000 – Silicic acid, silylated, Ref-No. 86285 – Silicon dioxide, silanated.

Switzerland – SR 817.023.21 – Annex 2 – Additives for plastics – Table 1 – List of Additives; Ref.-No.: 86000 – Silicic acid, silylated, Ref-No. 86285 – Silicon dioxide, silanated.

Switzerland – SR 817.023.21 – Annex 9 – Additives for Silicones – Table 1 – List of Additives; Listed as substance – No. 8190 – Silicic acid, silanated.