

GelTech Soil2O Topical – Safety Information Human and Environmental

Soil2O Topical from GelTech is a superabsorbent polymer which meets the highest environmental and toxicological standards ensuring a work environment that carries no risk of human or animal exposure.

Superabsorbent polymers are used primarily as intermediate and raw materials in a variety of consumer and industrial products; the products are cross-linked polymers of partially neutralized acrylic acid. In the dry form the product is a fine powder of crystalline like structure. Upon swelling with water, it yields a gel. The retention of water is facilitated by the negative carboxylic groups of the polymer and their hydration with water molecules, due to its crosslinking the product is essentially insoluble in water.

Soil2O Topical complies with all regulatory requirements under Federal, State, and local agencies that oversee both laboratory testing and working environment human health and safety concerns. Soil2O Topical exceeds all plausible standards of human exposure including approval as a food additive. This testing and approval process includes the Environmental Protection Agency (EPA), the Occupational Safety and Health Agency (OSHA), US Food and Drug Administration (FDA), United States Department of Agriculture (USDA), Mine Safety and Health Administration (MSHA) as well as recognized third party laboratories and testing facilities.

Soil2O Topical is a superabsorbent polymer which exhibits a low toxicological profile. Under appropriate test conditions there have been no signs of acute oral toxicity and no acute dermal toxicity. Furthermore, sub-acute oral toxicity and sub chronic dermal toxicity have not been observed. The eye irritation potential is very low and the product has a good compatibility following systemic injection or implantation and towards blood. It is not per se cytotoxic. Absorption after oral uptake is negligible. Some absorption is observed after intra tracheal application in the dry powder state but without any systemic toxicity. The product shows no evidence of an allergic contact sensitization in guinea pigs and humans. The same applies for irritative properties. No mutagenic and teratogenic potency was found. GelTech / Soil2O Topical does not serve as a growth substrate for pathogenic microorganisms therefore it can be assumed that the product is deemed safe for ingestion by animals or to be in contact with food for human consumption as outlined in Sec 177.1211 Cross-linked polyacrylate copolymers.

The presented eco toxicological and environmental studies were performed according to international recognized test methods and in compliance with the Principles of Good Laboratory Practice (GLP) by the United States government regulatory agencies responsible for the testing and approval of the superabsorbent polymer marketed under the name Soil2O Topical.

Additional independent laboratory findings are included where applicable or requested in addition to required testing performed by government regulatory agencies.

Soil₂O Topical

Soil₂O Topical is a sodium polyacrylate material that is used extensively in the agricultural industry and is infused in the soil of many potted plants to help them retain moisture, behaving as a type of water reservoir. Florists commonly use sodium polyacrylate to help keep flowers fresh, and this substance has been approved for domestic fruit and vegetable growing by the U.S. Department of Agriculture. Sodium polyacrylate is a polymer, meaning that it consists of chains of identical units (monomers).

The monomer for sodium polyacrylate is: $--CH_2--CH(CO_2Na)--$

Unlike Polyvinyl Acetate which is:

Polyvinyl acetate, PVA, PVAc, poly(ethenyl ethanoate), is a rubbery synthetic polymer with the formula $(C_4H_6O_2)_n$. It belongs to the polyvinyl esters family with the general formula $-[RCOOCH_2CH]_n-$. It is a type of thermoplastic.[1]

Superabsorbent polymers are used primarily as intermediate and raw materials in a variety of consumer and industrial products including treatment of municipal waste water. The testing and approval process includes the, the Occupational Safety and Health Agency (OSHA), US Food and Drug Administration (FDA), United States Department of Agriculture (USDA), Mine Safety and Health Administration (MSHA) as well as recognized third party laboratories and testing facilities. The product has been tested as a food additive and carries approvals to be in contact with food for human consumption. Although best practices should be maintained when working with all products the product poses no exposure risks as defined by the FDA.



The following are complete government verified data sets showing the results of the provided health and environmental information:

Acute oral toxicity

Up to 5 % mixed solution applied as gel in saline was applied once with a stomach tube to 5 male and 5 female rats each. No abnormal findings were evident at any time point during examinations over 14 days. Bodyweight development was normal; necropsy revealed no visible organ alterations. The LD50 was > 5,000 mg/kg body weight. Application of an aqueous extract of the SAP to 6 male and 6 female rats with the drinking water for 1 day led to no adverse effects. Deaths did not occur and no visible organ changes were detected. Neither the polymer nor the mixed solution is of acute toxicity after oral administration.

Subacute oral toxicity

The oral toxicity of mixed gel, administered daily to 10 male and 10 female rats per group via the diet over consecutive weeks at concentrations of up to 5 % was investigated. No toxicologically significant changes were induced. The differences observed between treated and control animals were modifications in urinary ion excretion in the treated animals. Both findings were considered to be related to the relatively high concentration of sodium in the test substance and therefore of no toxicological relevance.

HET-CAM-Test

The hen's egg test is an alternative test method to the Draize rabbit eye test. For this test 200 mg of dry product, the swollen gel or an extract were applied onto the sensitive chorioallantoic membrane (CAM) of the developing chicken egg. There were only slight irritative effects leading to vascular injection but no adverse effects with respect to hemorrhaging, or coagulation. Thus the potential of the product to cause adverse effects on membranes seems to be very low.

Cytotoxicity in vitro

The product was examined regarding its influence on mammalian cells in a cell culture system using 3T3 fibroblasts of mice. The cells were incubated for 24 hours with an extract of the product in concentrations up to 1.5 % (v/v) in cell culture medium. No adverse effects on the morphology or viability of the cells were observed. Extraction of product with cell culture medium (10 g/medium) led to a concentration dependent decrease in cell viability due to complex formation (binding) of essential cations in the medium. Following supplementation of the bound cations, adverse effects were not observed any longer. Further cell toxicity tests were executed using the agar diffusion cell culture technique, which is appropriate for solid specimens as well. The product was applied as dry granulate and as a suspension (30 g/l saline). There was no indication of cytotoxic effects.

Intravenous and intra peritoneal application

Intravenous and intra peritoneal compatibility of SAP was tested after systemic injection in mice. Following intra peritoneal application of 50 ml/kg extract in sesame oil or 10 g/kg extract in polyethylene glycol no toxic reactions of the animals were observed within 72 hours.

Intravenous instillation of a gel extract (15 g/l saline) produced systemic effects and mortality in dose levels greater than 40 ml/kg. Histopathological examination revealed dose dependent toxic alterations of liver and spleen. The no observed effect level (NOEL) was less than 10 ml/kg, a dose which led only to minimal hepatic effects.

Subcutaneous and intramuscular implantation

Subcutaneous and intramuscular compatibility of a gel and the granulate of product was tested in rabbits after implantation. Histopathology revealed no abnormal reactions in the surrounding tissue. Furthermore, there were no significant deviations from normal values in hematology, clinical chemistry, and other standard toxicological parameters. No signs of toxicity were observed.

Escherichia coli reverse mutation assay

Extracts of the product were tested in tryptophan requiring strains of Escherichia coli for their ability to induce point mutations in the absence or presence of a metabolic activation system. In concentrations of up to 5,000 µg/plate no mutagenic events could be observed. Furthermore, no cytotoxicity was detected.

UDS in rat hepatocytes in vitro

The product was tested for its ability to induce unscheduled DNA synthesis (UDS) in isolated rat hepatocytes in vitro. Treatment with up to 1,500 µg/ml of equivalent extracted material in saline with 10 % (v/v) ethanol did not produce a mean net grain count greater than zero (0), nor were 20 % or more cells to be found in repair. The test substance therefore showed no genotoxic activity.

Teratogenicity

Pregnant female rats were exposed in a teratology study to respirable levels (particle size < 10 µm) of product at 0.3, 1.0 and 10 mg/m³ for 6 hours/day from day 6 to day 15 of gestation. On day 20 of gestation the rats were necropsied and examined for the number of implantations, early and late resorptions, live and dead fetuses and number of corpora lutea. The fetuses were observed for weight, external, soft tissue and skeletal alterations. No effects were detected: The highest test concentration is the no observed effect level (NOEL).

The following information has been compiled from sources believed to be reliable and is accurate to the best of our knowledge. However, GelTech Solutions® cannot give guarantees regarding information from other sources, and expressly do not make any warranties, nor assume any liability for its use.

[Title 21, Volume 3]

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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN

SERVICES (CONTINUED)

PART 177--INDIRECT FOOD ADDITIVES:
POLYMERS--Table of Contents

Subpart B--Substances for Use as Basic Components of Single and
Repeated

Use Food Contact Surfaces

Sec. 177.1211 Cross-linked polyacrylate copolymers.

Cross-linked polyacrylate copolymers identified in paragraph (a) of this section may be safely used as articles or components of articles intended for use in contact with food in accordance with the following prescribed conditions: (a) Identity. For the purpose of this section, the cross-linked polyacrylate copolymers consist of:

(1) The grafted copolymer of cross-linked sodium polyacrylate identified as 2- propenoic acid, polymers with N,N-di-2-propenyl-2-propen-1-amine and hydrolyzed polyvinyl acetate, sodium salts, graft (CAS Reg. No. 166164-74-5); or

2-propenoic acid, polymer with 2-ethyl-2-(((1-oxo-2-propenyl)oxy)methyl)- 1,3-propanediyl di-2-propenoate and sodium 2-propenoate (CAS Reg. No. 76774-25-9). (b) Adjuvants. The copolymers identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of such copolymers. The optional adjuvant substances may include substances permitted for such use by regulations in parts 170 through 179 of this chapter, substances generally recognized as safe in food, and substances used in accordance with a prior sanction or approval.

(c) Extractives limitations. The copolymers identified in paragraph (a) of this section, in the finished form in which they will contact food, must yield low molecular weight (less than 1,000 Daltons) extractives of no more than 0.15 percent by weight of the total polymer when extracted with 0.2 percent by weight of aqueous sodium chloride solution at 20 deg.C for 24 hours. The low molecular weight extractives shall be determined using size exclusion chromatography or an equivalent method. When conducting the extraction test, the copolymer, with no other absorptive media, shall be confined either in a finished absorbent pad or in any suitable flexible porous article, (such as a “tea bag” or infuser), under an applied pressure of 0.15 pounds per square inch (for example, a 4x6 inch square pad is subjected to a 1.6 kilograms applied mass). The solvent used shall be at least 60 milliliters aqueous sodium chloride solution per gram of copolymer.

(d) Conditions of use. The copolymers identified in paragraph (a)(1) of this section are limited to use as a fluid absorbent in food-contact materials used in the packaging of frozen or refrigerated poultry. The copolymers identified in paragraph (a)(2) of this section are limited to use as a fluid absorbent in foodcontact materials used in the packaging of frozen or refrigerated meat and poultry.

[64 FR 28098, May 25, 1999, as amended at 65 FR 16817, Mar. 30, 2000]