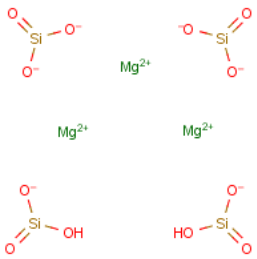
Talcum

Ingredient synonym names

Agalite, Alpine talc USP, bc 127, Asbestine, B 13, B 13 (mineral)
B 9, Beaver White 200, CI 77718, CP 10-40, CP 38-33, Crystalite CRS 6002, Desertalc 57, EX-IT, Emtal 500, Emtal 549, Emtal 596, Emtal 599, FW-XO, Fibrene C 400, Finntalc C10, Finntalc M05, Finntalc M15, Finntalc P40, Finntalc PF, French chalk, HSDB 830, Hydrous magnesium silicate, IT Extra, LMR 100, Lo Micron talc USP, bc 2755, MP 12-50, MP 25-38, MP 40-27, MP 45-26, MST, Magnesium silicate talc, Magnesium silicate, hydrous, Micro Ace K1, Micro Ace L1, Micron White 5000A, Micron White 5000P, Micron White 5000S, Microtalco IT Extra, Mistron 139, Mistron 2SC, Mistron RCS, Mistron Star, Mistron frost P, Mistron super frost, Mistron vapour, Mussolinite, NCI-C06008, Nonasbestiform talc, Nonfibrous talc, Nytal 200, Nytal 400, P 3, P 3 (Mineral), PK-C, PK-N, Polytal 4641, Polytal 4725, Sclerosol, Snowgoose, Soapstone, Steatite, Steatite talc, Steawhite, Supreme, Supreme dense, TY 80, Talc, Talc (Mg3H2(SiO3)4), Talc (powder), Talc (non-asbestos form), Talcan PK-P, Talcron CP 44-31, Talcum, UNII-7SEV7J4R1U

IDENTIFIER DETAILS

Ingredient chemical structure



CAS Number	FEMA Number	Additive Number	Ingredient EC Number
14807-96-6	-	-	238-877-9

CAS Additional Number	FL Number	CoE Number
110540-41-5 11119-41-8 12420-12-1 184973-42-0 37232-12-5 8043-56-9 99638-63-8	-	-

Chemical formula H2-03-Si.3/4Mg

Ingredient CLP Classification

Ingredient REACH Registration Number

-

Acute Oral Toxicity	Eye Damage/Irritation	Carcinogenity
0	0	0

Acute Dermal Toxicity	Respiratory Sensitisation	Reproductive Toxicity
0	0	0

Acute Inhalation Toxicity	Skin Sensitisation	Aspiration Toxicity
0	0	0

Talcum

Skin Corrosive/Irritant	Mutagenicity/ Genotoxicity	Specific Target Organ Toxicity
0	0	0

SPECIFICATIONS

Melting Point	-	Boiling Point	-

STATUS IN FOOD AND DRUG LAWS

Acceptable Daily Intake (ADI, mg/kg)	No data identified
Acceptable Daily Intake (ADI) comments	No data identified
FDA Status	Talc has GRAS status. According to the Select Committee on GRAS substances reviews (1979) there is no data to suggest that Talc (non-asbestiform) or magnesium silicate cannot continue to be used at current levels or those reasonably expected in the future. [http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=scogsListing&id=345]

CoE limits - Beverages (mg/kg)	-	CoE limits - Food (mg/kg)	-	CoE limits - Exceptions (mg/kg)	-

HUMAN EXPOSURE

Ingredient Natural Occurence (if applicable)

Talc is a native hydrous magnesium silicate [Toxnet, 2009], it is often milled before use.

References - Ingredient Natural Occurence

ToxNet, searched 2009. http://toxnet.nlm.nih.gov/

Ingredient Reported Uses

Commonly used as a dusting powder, alone or combined with starch or boric acid, for pharmaceutical or toilet preparations. It is also used as a filler for pills/tablets and for dusting of moulds [ToxNet, 2009].

References - Ingredient Reported Uses

ToxNet, searched 2009. http://toxnet.nlm.nih.gov/

TOXICITY DATA

In Vivo Data

Acute Toxicity Data

No data identified

In Vivo Carcinogenicity/Mutagenicity

The HSDB database further references an IARC monograph that reviews the literature relevant to carcinogenicity risk of Talc with and without asbestiform fibres. The review concludes that whilst there is insufficient data in animal models there is sufficient data from human exposure to designate non-asbestiform talc as 'Class 3 – the agent is classifiable as to its carcinogenicity to humans'. It is noted however that talc is often contaminated with other minerals (i.e. quartz, serpentines and amphiboles (asbestiform and non-asbestiform)) and it is these that seem to be associated with increased carcinogenicity risk [IARC, 1987]. A review by Wild (2006) also suggests that high levels of talc exposure are not associated with increased risk of lung cancer mortality, but when talc exposure is combined with other potential carcinogens 'some lung cancer excesses were observed' [Wild, 2006].

In the CCRIS database a National Toxicology Programme (NTP) carcinogenicity study was identified for Talc inhalation [NTP, 1993]. A summary is provided in the following table. It should be noted that the authors highlighted a problem in aerosol generation that lasted for 7 weeks in the rat study, but the NTP study concluded that:

'Under the conditions of these inhalation studies, there was some evidence of carcinogenic activity of talc in male F344/N rats based on an increased incidence of benign or malignant pheochromocytomas of the adrenal gland. There was clear evidence of carcinogenic activity of talc in female F344/N rats based on increased incidences of alveolar/bronchiolar adenomas and carcinomas of the lung and benign or malignant pheochromocytomas of the adrenal gland. There was no evidence of carcinogenic activity of talc in male or female B6C3F1 mice exposed to 6 or 18 mg/cu m' [NTP, 1993].

Additional in vivo CMR data on Talc:
Species - Rat, F344/Male,
Dose - 0; 6; 18 MG/M3 6 HR/D 5 D/WK FOR 113 WK (STUDY DURATION: 114 WK)
Tumour site - ADRENAL MEDULLA: BENIGN, MALIGNANT OR COMPLEX PHEOCHROMOCYTOMA
Results - POSITIVE
Reference - [NCI/NTP]

Species - Rat
Strain/Sex - F344/Female
Dose - 0; 6; 18 MG/M3 6 HR/D 5 D/WK FOR 122 WK (STUDY DURATION: 123 WK)
Tumour site - ADRENAL MEDULLA: BENIGN OR MALIGNANT PHEOCHROMOCYTOMA; LUNG: ALVEOLAR/BRONCHIOLAR ADENOMA, ALVEOLAR/BRONCHIOLAR CARCINOMA
Result - POSITIVE
Reference - [NCI/NTP]

Species - Mouse
Strain/Sex - B6C3F1/Male
Dose - 0; 6; 18 MG/M3 6 HR/D 5 D/WK FOR 103-104 WK (STUDY DURATION: 106 WK)
No tumours
Result- Negative
Reference - [NCI/NTP]

Species - Mouse
Strain/Sex - B6C3F1/Female
Dose - 0; 6; 18 MG/M3 6 HR/D 5 D/WK FOR 103-104 WK (STUDY DURATION: 106 WK)
No tumours
Result - Negative
Reference - [NCI/NTP]

References - In Vivo Carcinogenicity/Mutagenicity

IARC (1987). Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man. Geneva: World Health Organization, International Agency for Research on Cancer, 1972-PRESENT. (Multivolume work), p.S7 72.

Keskın N, Teksen YA, Ongun EG, Ozay Y, Saygılı H (2009). Does long-term talc exposure have a carcinogenic effect on the female genitalsystem of rats? An experimental pilot study. Arch Gynecol Obstet, Mar 20.

NCI/NTP Carcinogenesis technical report series; National Cancer Institute/National Toxicology Program; U.S. Department of Health and Human Services, TR-421 Y93

NTP, (1993). Toxicology & Carcinogenesis Studies of Talc (Non-Asbestiform in F344/N Rats and B6C3F1 Mice (Inhalation Studies). Technical Report Series No. 421 NIH Publication No. 93-3152 U.S. Department of Health and Human Services, National Toxicology Program, National Institute of Environmental Health Sciences, Research Triangle Park, NC 27709 (via CCRIS database).

Wild, P (2006). Lung cancer risk and talc not containing asbestiform fibres: a review of the epidemiological evidence. Occup Environ Med, 63:4–9.

Dermal Toxicity

No data identified.

References - Dermal Toxicity

No data identified.

Reproductive/ Developmental Toxicity

A study by Keskin et al (2009) investigated the histopathological changes in the genital organs of female rats since there is some ambiguity in the literature with regards to potential carcinogenic effects. Twenty-eight Sprague-Dawley rats (4 groups of 7 rats), groups were as follows; group 1, no intervention, group 2, intravaginal saline, group 3, intravaginal talc and group 4, perineal talc application. Talc was applied for 3 months daily. The authors state that in group 1, five rats were normal, two developed infections within the genital organs. In Group 2, only one experimental animal had endometritis. All the animals in Groups 3 and 4 developed infections. No neoplastic changes were observed, although there was some follicle formation. The authors concluded that the effect of talc ‘is in the form of foreign body reaction and infection, rather than being neoplastic’ [Keskin et al, 2009].

References - Reproductive/ Developmental Toxicity

Keskın N, Teksen YA, Ongun EG, Ozay Y, Saygılı H (2009). Does long-term talc exposure have a carcinogenic effect on the female genitalsystem of rats? An experimental pilot study. Arch Gynecol Obstet, Mar 20. [Epub ahead of print].

Inhalation Toxicity

The HSDB database references a study in ‘Patty’s Toxicology Volumes 1-9, 5th edition, 2001’ that shows that in hamsters the half-life of talc deposited in the alveoli was found to be 7-10 days, with alveolar clearance complete within 4 months post-exposure [HSDB, 2009].

A potential outcome of talc inhalation is pneumoconiosis, disease pathology differs depending on the contaminants in the talc but disease resulting from exposure to pure is called talcosis. Chung et al (2006) state that radiographic analysis of the lungs of talcosis patients usually shows large opacities that resemble those in

progressive massive fibrosis. Furthermore thin-section CT show ‘small centrilobular and subpleural nodules and heterogeneous conglomerate masses with internal foci of high attenuation that are consistent with talc deposition [Chung et al, 2006].

References - Inhalation Toxicity

Chung S, Lee KS, Chung MJ, Han J, Kwon OJ, Kim TS (2006). Pneumoconiosis: comparison of imaging and pathologic findings. Radiographics, 26(1):59-77.

HSDB,(2009).http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~weHpSH:1

Cardiac Toxicity

No data identified.

References - Cardiac Toxicity

No data identified.

Addictive Data

No data identified.

References - Addictive Data

No data identified.

Behavioral data

No data identified.

References - Behavioral data

No data identified.

In Vivo - Other Relevant Studies

Talc slurry is can be used in humans to prevent pneumothorax and plural effusion, via instillation into the fluid filled pleural space and is called pleurodesis. A review by Genofre et al (2007) showed that this treatment can cause chest pain, fever, arrhythmias, and dyspnea. Systemic inflammation can also result from this treatment and severity is associated with a higher proportion of finer talc particles, which migrate into the blood stream and organs [Genofre et al, 2007].

References - In Vivo - Other Relevant Studies

Genofre EH, Marchi E, Vargas FS (2007). Inflammation and clinical repercussions of pleurodesis induced by intrapleural talc administration. Clinics (Sao Paulo), 62(5):627-34.

In Vitro Data

In Vitro Carcinogenicity/Mutagenicity

In the CCRIS database three studies were identified assessing the carcinogenic and mutagenic potential of talc using in vitro systems. The results are presented as: Test System - Strain - Metabolic Activation - Method - Dose -

Result - Reference [CCRIS, 2009].

Ames Salmonella typhimurium - TA97 - None - Pre-incubation - 0-10 mg/plate (material in DMSO) - Negative - [Fujita et al., 1988]

Ames Salmonella typhimurium - TA109 - None - Pre-incubation - 0-10 mg/plate (material in DMSO) - Negative - [Fujita et al., 1988]

Ames Salmonella typhimurium - TA97 - S-9 - Pre-incubation - 0-10 mg/plate (material in DMSO) - Negative - [Fujita et al., 1988]

Ames Salmonella typhimurium - TA102 - S-9 - Pre-incubation - 0-10 mg/plate (material in DMSO) - Negative - [Fujita et al., 1988]

UDS Rat Pleural Mesothelial Cells - THY INCORP - None - Scintillation counting - 10-50 µg/cm2 - Negative - [Endo-Capron et al. 1993]

Ames Salmonella typhimurium - TA100 - None - No data - 0-20 mg/plate (material in DMSO) - Negative - [Sofuni et al. 1994]

Ames Salmonella typhimurium - TA1535 - None - No data - 0-20 mg/plate (material in DMSO) - Negative - [Sofuni et al. 1994]

Ames Salmonella typhimurium - TA1535 - S-9 - No data - 0-20 mg/plate (material in DMSO) - Negative - [Sofuni et al. 1994]

Ames Salmonella typhimurium - TA98 - None - No data - 0-20 mg/plate (material in DMSO) - Negative - [Sofuni et al. 1994]

Ames Salmonella typhimurium - TA98 - S-9 - No data - 0-20 mg/plate (material in DMSO) - Negative - [Sofuni et al. 1994]

Ames Salmonella typhimurium - TA1537 - None - No data - 0-20 mg/plate (material in DMSO) - Negative - [Sofuni et al. 1994]

Ames Salmonella typhimurium - TA1537 - S-9 - No data - 0-20 mg/plate (material in DMSO) - Negative - [Sofuni et al. 1994]

Ames Salmonella typhimurium - TA1538 - None - No data - 0-20 mg/plate (material in DMSO) - Negative - [Sofuni et al. 1994]

Ames Salmonella typhimurium - TA1538 - S-9 - No data - 0-20 mg/plate (material in DMSO) - Negative - [Sofuni et al. 1994]

References - In Vitro Carcinogenicity/Mutagenicity

CCRIS, (2009). http://toxnet.nlm.nih.gov/cgi-bin/sis/search

Endo-Capron, S., Reniew, A., Janson, X., Kheuang, L., Jaurand, M. C. (1988). In vitro response of rat pleural mesothelial cells to talc samples in genotoxicity assays (sister chromatid exchanges and DNA repair). Toxicol. In Vitro 7(1): 7-14

Fujita, H., Nakano, M., Sasaki, M. (1998). Mutagenicity test of food additives with Salmonella typhimurium TA97 and TA102 III; Kenkyu Nenpo-Tokyo-Toritsu Eisei Kenkynsho (39):343-50

Sofuni, T. (1994). Mutagenicity tests on food additives (Series 12). Collaborative Study Supported by the Ministry of Health and Welfare of Japan; Hen'Igensei Shiken 3(4):206-215

In Vitro - Other Relevant Studies

A review. The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) provides a scientific opinion re-evaluating the safety of calcium silicate (E 552), magnesium silicate (E 553a) and talc (E 553b) when used as food additives. In 1991, the Scientific Committee on Food (SCF) established a group acceptable daily intake (ADI) 'not specified' for silicon dioxide and silicates. The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) recently provided a scientific opinion re-evaluating the safety of silicon dioxide (E 551) when used as a food additive. The Panel noted that the absorption of silicates and talc was very low; there was no indication for genotoxicity or developmental toxicity for calcium and magnesium silicate and talc; and no confirmed cases of kidney effects have been found in the EudraVigilance database despite the wide and long-term use of high doses of magnesium trisilicate up to 4 g/person per day over decades. However, the Panel considered that accumulation of silicon from calcium silicate in the kidney and liver was reported in rats, and reliable data on subchronic and chronic toxicity, carcinogenicity and reproductive toxicity of silicates and talc were lacking. Therefore, the Panel concluded that the safety of calcium silicate (E 552), magnesium silicate (E 553a(i)), magnesium trisilicate (E 553a(ii)) and talc (E 553b) when used as food additives cannot be assessed. The Panel considered that there is no mechanistic rationale for a group ADI for silicates and silicon dioxide and the group ADI established by the SCF is obsolete. Based on the food supplement scenario considered as the most representative for risk characterization, exposure to silicates (E 552-553) for all population groups was below the maximum daily dose of magnesium trisilicate used as an antacid (4 g/person per day). The Panel noted that there were a number of approaches, which could decrease the uncertainties in the current toxicological database. These approaches include - but are not limited to - toxicological studies as recommended for a Tier 1 approach as described in the EFSA Guidance for the submission of food additives and conducted with an adequately characterized material. Some recommendations for the revision of the EU specifications were proposed by the Panel. [EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), (2018)]

References - In Vitro - Other Relevant Studies

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), Younes, M., Aggett, P., Aguilar, F., Crebelli, R., Dusemund, B., ... & Gundert-Remy, U. (2018). Re-evaluation of calcium silicate (E 552), magnesium silicate (E 553a (i)), magnesium trisilicate (E 553a (ii)) and talc (E 553b) as food additives. EFSA Journal, 16(8), e05375.

Emissions and Associated Toxicity Data

No data identified.

References - Emissions and Associated Toxicity Data

No data identified.