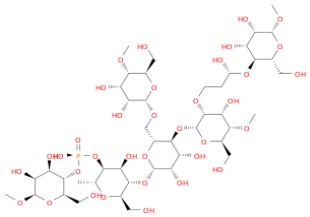
Starch, phosphate, Phosphated distarch phosphate

Ingredient synonym names

Starch, phosphate

Phosphated distarch phosphate

IDENTIFIER DETAILS

CAS Number	FEMA Number	Additive Number	Ingredient EC Number	Ingredient chemical structure
11120-02-8	NF	1413	-	

CAS Additional Number	FL Number	CoE Number
11120-02-8		NR

Chemical formula	
$C_{44}H_{79}O_{35}P$	

Ingredient CLP Classification

Ingredient REACH Registration Number
In Pre-registration

Acute Oral Toxicity	Eye Damage/Irritation	Carcinogenity
N/A	N/A	N/A
Acute Dermal Toxicity	**Respiratory Sensitisation**	**Reproductive Toxicity**
N/A	N/A	N/A
Acute Inhalation Toxicity	**Skin Sensitisation**	**Aspiration Toxicity**
N/A	N/A	N/A
Skin Corrosive/Irritant	**Mutagenicity/ Genotoxicity**	**Specific Target Organ Toxicity**
N/A	N/A	N/A

SPECIFICATIONS

Starch, phosphate, Phosphated distarch phosphate

Melting Point	-	Boiling Point	-

STATUS IN FOOD AND DRUG LAWS

Acceptable Daily Intake (ADI, mg/kg)	Not Specified
Acceptable Daily Intake (ADI) comments	**Evaluation year:** 2018 Comments: Considered for specification only. Meeting: 86 Specs Code: R, T Report: TRS 1014-JECFA 86/65 Specification: FAO JECFA Monographs 22/53
FDA Status	NL

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

HUMAN EXPOSURE

Ingredient Natural Occurence (if applicable)

Starches for commercial use are generally produced from potatoes, cereals or other sources. In modified starches, the chemical and physical characteristics of the native substances are altered in order to improve the functional properties for particular food applications: the observed effects on such properties depend on the type and extent of the modification (e.g. degree of substitution (DS)) and the source starch (e.g. cereal, potato, tapioca).

References - Ingredient Natural Occurence

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), Mortensen A, Aguilar F, et al. Re-evaluation of oxidised starch (E 1404), monostarch phosphate (E 1410), distarch phosphate (E 1412), phosphated distarch phosphate (E 1413), acetylated distarch phosphate (E 1414), acetylated starch (E 1420), acetylated distarch adipate (E 1422), hydroxypropyl starch (E 1440), hydroxypropyl distarch phosphate (E 1442), starch sodium octenyl succinate (E 1450), acetylated oxidised starch (E 1451) and starch aluminium octenyl succinate (E 1452) as food additives. *EFSA J*. 2017;15(10):e04911. Published 2017 Oct 5. doi:10.2903/j.efsa.2017.4911

Ingredient Reported Uses

Starch, phosphate, Phosphated distarch phosphate

Starch typically consists of two polymers of glucose, namely amylose, with an almost linear structure, and amylopectin, which is highly branched. In amylose, the glucose monomers (pyranosic form) are linked by a-1,4-glycosidic links, while amylopectin contains additionally a-1,6-glycosidic bonds. Commercial starches are composed of about 20–25% amylose and 75–80% amylopectin. High amylose starches typically consist of 50–80% amylose and 20–50% amylopectin. Starches for commercial use are generally produced from potatoes, cereals or other sources. In modified starches, the chemical and physical characteristics of the native substances are altered in order to improve the functional properties for particular food applications: the observed effects on such properties depend on the type and extent of the modification (e.g. degree of substitution (DS)) and the source starch (e.g. cereal, potato, tapioca). In general, the extent of modification required to distinctly alter the functional characteristics of native starches is low, as imposed by Commission Regulation (EU) No 231/2012. In conclusion, for a large number of food applications, modified starches are used because of their superior properties compared to the native substances [...] Monostarch phosphate is starch esterified with orthophosphoric acid, or sodium or potassium orthophosphate or sodium tripolyphosphate. Based on structural evaluations, the phosphoric ester groups are mainly attached to C-6 and to a lesser extent to C-2 and C-3 of the glucopyranose units. [...] Compared to native starch, the starch phosphates display greater water solubility and water-binding capacity, and both characteristics increase with increasing phosphate substitution (Fortuna et al., 1990). Phosphorylation causes higher viscosities and greater clarity of the dispersions (Wurzburg, 2006). Higher degrees of phosphate lower the pasting temperature, while maximum viscosity is slightly increased (Fortuna et al., 1990).

References - Ingredient Reported Uses

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), Mortensen A, Aguilar F, et al. Re-evaluation of oxidised starch (E 1404), monostarch phosphate (E 1410), distarch phosphate (E 1412), phosphated distarch phosphate (E 1413), acetylated distarch phosphate (E 1414), acetylated starch (E 1420), acetylated distarch adipate (E 1422), hydroxypropyl starch (E 1440), hydroxypropyl distarch phosphate (E 1442), starch sodium octenyl succinate (E 1450), acetylated oxidised starch (E 1451) and starch aluminium octenyl succinate (E 1452) as food additives. *EFSA J*. 2017;15(10):e04911. Published 2017 Oct 5. doi:10.2903/j.efsa.2017.4911

TOXICITY DATA

In Vivo Data

Acute Toxicity Data

-

In Vivo Carcinogenicity/Mutagenicity

A chronic feeding study was carried out in mice with two chemically modified potato starches, hydroxypropyl distarch phosphate (HP-starch) and starch acetate (AC-starch), and with lactose and sodium alginate. Each of the materials was fed to a group of 75 male and 75 female mice for 89 wk. The dietary level of the test products was gradually increased until the diets contained (by weight) 55% HP-starch, 55% AC-starch, 55% lactose or 25% alginate. The control diet contained 55% pregelatinized potato starch. Each of the four test materials caused increased water consumption, distinct caecal and colonic enlargement, a slightly increased incidence of intratubular nephrosis and, with the exception of AC-starch, also slightly lower body weights. An increased incidence of gastric trichobezoars was observed in mice fed either the modified starches or lactose. The occurrence of concrements in the renal pelvis along with slight urinary changes, such as increased amounts of amorphous material in the urine and increased urinary Ca content, in mice fed HP-starch, AC-starch or lactose was regarded as an effect of little, if any, toxicological significance. Alginate fed at 25% (w/w) of the diet was nephrotoxic to mice, as shown by extremely high water consumption, high urine production, urinary incontinence, high pH and low specific gravity of the urine, increased level of blood urea nitrogen, increased kidney weights, distension of the renal calyx and the high incidence of dilated distal tubules. Caecal and colonic enlargement and changes in urinalysis were found to be reversible and had completely or largely disappeared within 2–5 wk of the cessation of the treatment in wk 87. The incidence of intratubular calcinosis or of concrements in the pelvic space was not reduced during the recovery period. The study did not provide any evidence of carcinogenicity of the products tested (Til, *et al*., 1986).

References - In Vivo Carcinogenicity/Mutagenicity

Til, H. P., Feron, V. J., Immel, H. R., & Vogel, W. F. (1986). Chronic (89-week) feeding study with hydroxypropyl distarch phosphate, starch acetate, lactose and sodium alginate in mice. *Food and chemical toxicology*, *24*(8), 825-834.

Dermal Toxicity

Starch, phosphate, Phosphated distarch phosphate

No Data Identified

References - Dermal Toxicity

No Data Identified

Reproductive/ Developmental Toxicity

Five chemically modified starches, acetylated distarch phosphate, acetylated diamylopectin phosphate, starch acetate, hydroxypropyl distarch glycerol and phosphated distarch phosphate, were fed to rats at dietary levels of 0 (control), 5, 10 and 30% for 2 yr and at one level, 10%, over three generations. In the 2-yr study, no adverse effects were observed on mortality, food intake, haematology, blood biochemistry or urine composition. Each of the modified starches examined, except the phosphated distarch phosphate, slightly reduced body weights at the 30% level and caused distinct caecal enlargement at 10 and 30%, but the microscopic structure of the caecal wall was normal. In comparison with the controls, the males fed the 30% level of any of the modified starches showed a slightly increased degree and incidence of focal hyperplasia of the renal papillary and pelvic epithelium, accompanied by calcified patches in the underlying tissue. The studies did not provide any indication of carcinogenicity. The multigeneration study showed no effect on fertility, on lactation performance or on embryonic or pre-weaning mortality. Extensive microscopic examination of the F_{3b}-generation rats failed to reveal any changes attributable to treatment. It was concluded that the feeding of each of the modified starches at dietary levels up to 30% for 2 yr and at a level of 10% over three generations did not result in any distinct effect of toxicological significance (De Groot, *et al*., 1974).

References - Reproductive/ Developmental Toxicity

De Groot, A. P., Til, H. P., Feron, V. J., Dreef-van der Meulen, H. C., & Willems, M. I. (1974). Two-year feeding and multigeneration studies in rats on five chemically modified starches. *Food and cosmetics toxicology*, *12*(5-6), 651-663.

Inhalation Toxicity

No Data Identified

References - Inhalation Toxicity

No Data Identified

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

Starch, phosphate, Phosphated distarch phosphate

The relation of cecal enlargement to the feeding of raw and modified starch [9005-25-8] was studied. Small differences in cecal size reflected an adaptive change to differences in diet, and were of toxicol. significance only when gross effects were accompanied by secondary nutritional and toxicol. changes. The adverse effects were correlated with extreme resistance to pancreatic amylase, which is eliminated by pregelatinization of the starches. With the food-grade starch phosphate [11120-02-8] samples, there were no adverse effects on cecal size, and they were readily hydrolyzed by amylase. (Walker, R., 1978).

Data on in vitro degradation of modified starches by digestive enzymes indicated that their digestibility was slightly reduced or showed no differences when compared to corresponding unmodified starches. In vivo data are in agreement with in vitro studies indicating that the two major components of starches, amylose and amylopectin, would be fermented during their passage through the large intestine by strains of bacteria found in the human colon. The main end products of this colonic anaerobic digestive process are short-chain fatty acids (SCFA) such as acetic, propionic and butyric acids, which are absorbed from the colon. Despite the absence of absorption, distribution, metabolism and excretion (ADME) data for two modified starches (E 1451 and E 1452) and the absence of in vivo studies in humans for some other modified starches, the Panel considered this database sufficient to conclude that modified starches would not be absorbed intact but significantly hydrolysed by intestinal enzymes and then fermented by intestinal microbiota in humans (EFSA, 2017).

References - In Vivo - Other Relevant Studies

Walker, R. From Developments in Toxicology and Environmental Science (1978), 3(Chem. Toxicol. Food), 3…

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), Mortensen A, Aguilar F, et al. Re-evaluation of oxidised starch (E 1404), monostarch phosphate (E 1410), distarch phosphate (E 1412), phosphated distarch phosphate (E 1413), acetylated distarch phosphate (E 1414), acetylated starch (E 1420), acetylated distarch adipate (E 1422), hydroxypropyl starch (E 1440), hydroxypropyl distarch phosphate (E 1442), starch sodium octenyl succinate (E 1450), acetylated oxidised starch (E 1451) and starch aluminium octenyl succinate (E 1452) as food additives. *EFSA J*. 2017;15(10):e04911. Published 2017 Oct 5. doi:10.2903/j.efsa.2017.4911

In Vitro Data

In Vitro Carcinogenicity/Mutagenicity

No Data Identified

References - In Vitro Carcinogenicity/Mutagenicity

No Data Identified

In Vitro - Other Relevant Studies

No Data Identified

References - In Vitro - Other Relevant Studies

No Data Identified

Emissions and Associated Toxicity Data

No Data Identified

References - Emissions and Associated Toxicity Data

No Data Identified