

Particle size of polyols

Polyols are sugar-free sweeteners that are widely used in the food industry to produce healthy alternatives to many traditional foods, usually known as 'sugar-free', 'no added sugar' or 'reduced sugar' products. Polyols are typically manufactured by hydrogenation and/or fermentation of different carbohydrates produced from renewable sources such as maize, wheat, tapioca, sugar beet, and milk.

Polyols are authorized *quantum satis* as food additives in the EU in accordance with Regulation (EC) 1333/2008 on food additives.¹ Same as for other food additives, the European Food Safety Authority (EFSA) is in charge of their safety assessment following strict rules laid down in Regulation (EC) 1331/2008.²

With the recent attention paid to the particle size of substances including food additives, EFSA published two guidance documents: Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health,³ and Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles.⁴

Polyols do not fall under the definition⁵ of nano-engineered material

- All polyols are manufactured by standard technological processes which include crystallisation, drying, crushing, milling, sifting and sieving which result in negligible amounts of particles smaller than 100 nm.
- To EPA's best knowledge and according to our literature search, nano-sized particles in polyols have no properties that are characteristic for the nanoscale.

As polyols do not fall under the definition of nano-engineered materials, the latter guidance⁴ provides structured pathway for carrying out safety assessment of the presence of a fraction of small particles in polyols. The guidance includes a decision process for selecting the applicable guidance document to be used as regards the risk assessment of small particles. As the first step the solubility test is considered. If the solubility of the substance in water is equal to or higher than 33.3 g/L, no additional assessment for the fraction of small particles is needed.

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R1333>

² <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1331>

³ <https://www.efsa.europa.eu/en/efsajournal/pub/6768>

⁴ <https://www.efsa.europa.eu/en/efsajournal/pub/6769>

⁵ Definition of nano-engineered material in Regulation (EU) No 1169/2011 on the provision of food information to consumers: <https://eur-lex.europa.eu/eli/reg/2011/1169/oj>

As shown in the table below, the solubility of all polyols is substantially higher than the threshold. Therefore, it can be concluded that there is no risk associated with the particle size of polyols and the assessment according to the sectoral guidance for food additives is sufficient.

Table 1. Data on solubility of polyols

Polyol	Commission regulation (EU) No 231/2012 as amended in 2017	Literature	
	Specification on Solubility	Solubility in water	source
Sorbitol (E 420)	Very soluble in water, slightly soluble in ethanol	2200 g/L at 20 °C	(1)
Mannitol (E 421)	Soluble in water, very slightly soluble in ethanol, practically insoluble in ether	216 g/L at 25 °C	(2)
Isomalt (E 953)	Soluble in water, very slightly soluble in ethanol	1000 g/L at 25 °C	(3)
Maltitol (E 965)	Very soluble in water, slightly soluble in ethanol	1000 g/L at 25 °C	(4)
Lactitol (E 966)	Very soluble in water	667 g/L at 25 °C	(5)
Xylitol (E 967)	Very soluble in water, sparingly soluble in ethanol	642 g/L at 25 °C	(6)
Erythritol (E 968)	Freely soluble in water, slightly soluble in ethanol, insoluble in diethyl ether.	610 g/L at 22 °C	(7)

- (1) <https://pubchem.ncbi.nlm.nih.gov/compound/5780#section=Solubility>
 (2) <https://pubchem.ncbi.nlm.nih.gov/compound/6251#section=Solubility>
 (3) <https://pubchem.ncbi.nlm.nih.gov/compound/88735#section=Solubility>
 (4) <https://pubchem.ncbi.nlm.nih.gov/compound/493591#section=Solubility>
 (5) <https://pubchem.ncbi.nlm.nih.gov/compound/157355#section=Solubility>
 (6) <https://echa.europa.eu/es/brief-profile/-/briefprofile/100.001.626>
 (7) <https://pubchem.ncbi.nlm.nih.gov/compound/222285#section=Solubility>