



Safety & Toxicity of Excipients For Paediatrics

### STEP Database Updated – 40 Excipients now!!!!

*[Alcohol, alpha-Cyclodextrin, Aspartame, Benzalkonium Chloride, Benzoic Acid, Benzyl Alcohol, beta-Cyclodextrin, Butylated Hydroxyanisole, Butylparaben, Carboxymethylcellulose, Carboxymethylcellulose Sodium, Crospovidone, Ethylparaben, gamma-Cyclodextrin, Glyceryl Monocaprylate [Capmul MCM C8], Hypromellose, Lactose, Mannitol, Methylparaben, Microcrystalline Cellulose, Polyethylene Glycol, Polysorbate 20, Polysorbate 40, Polysorbate 60, Polysorbate 65, Polysorbate 80, Povidone, Propylene Glycol, Propylparaben, Saccharin, Saccharin Sodium, Sodium Benzoate, Sodium Lauryl Sulfate, Sodium Metabisulphite, Sorbic acid, Sorbitol, Sucralose, Vitamin E Polyethylene Glycol Succinate, Xanthan Gum, Xylitol]*

The STEP stands for **S**afety and **T**oxicity of **E**xcipients for **P**aediatrics. It is a user-designed resource developed by European Paediatric Formulation Initiative (EuPFI) and United States Paediatric Formulation Initiative (USPFI) in collaboration for storage and rapid/effortless access to the safety and toxicological data of excipients that is scattered over various sources and presents it in one freely accessible source. It holds (1) General Information, (2) Clinical Data, (3) Non-Clinical Data, (4) In Vitro Data, (5) Regulatory References and (6) Reviews in relation to the safety and toxicity of excipients.

The pilot database with 10 excipients was launched in October 2014. The second & third version (with additional 20 excipients) was released last year. This is the fourth version released with new 10 excipients. In this updated version you will also see that we have designed the new login page with quick links to the database information. Also on basis of the usability study results we have made few changes to the search pages (eg. help icons, definition of search by excipient and search for excipient). We hope this will ease the use of the database. We are working to develop a webpage dedicated to all the information related the STEP database development such as information sources, search strategies etc and links to additional excipients information eg. update onEMA excipient labelling guidance revision, interesting articles on excipients in paediatrics etc.

The next dataset will be released by July 2016 [*Boric acid, Citric acid, Colloidal Silicon Dioxide, Butylated hydroxytoluene (BHT), , L-proline, Polaxmers, Maltitol, Magnesium Stearate, Sucrose, Trehalose*]

The focus of the ongoing project is to increase the number of excipients in the existing database so that a database large enough to be of practical research use will be available. For more information [including FAQs & Video tutorials] <http://www.eupfi.org/gpage11.html>

To include an excipient of your choice



Sponsor an excipient !

