

Extract from "**Table and List Guidance for Industry**" - U.S. Department of Health and Human Services/Food and Drug Administration

Solvents in Class 3 may be regarded as less toxic and of lower risk to human health. Class 3 includes no solvent known as a human health hazard at levels normally accepted in pharmaceuticals. However, there are no long-term toxicity or carcinogenicity studies for many of the solvents in Class 3.

**Class 3 Solvents Which Should Be Limited by GMP or Other Quality-Based Requirements**

Acetic acid  
Heptane  
Isobutyl acetate  
Anisole  
Isopropyl acetate  
1-Butanol  
Methyl acetate  
2-Butanol  
3-Methyl-1-butanol  
Butyl acetate  
Methylethyl ketone  
tert-Butylmethyl ether  
2-Methyl-1-propanol  
Dimethyl sulfoxide  
Pentane  
Ethanol  
1-Pentanol  
Ethyl acetate  
1-Propanol  
Ethyl ether  
2-Propanol  
Ethyl formate  
Propyl acetate  
Formic acid  
Triethylamine