

# Residual Solvents

## Xanthan Gum

Food & Pharmaceutical Grade

Product name	Xanthan Gum
EC No.	234-394-2
CAS No.	11138-66-2
E-No.	E 415

The content of this document is based on the requirements as defined in:

ICH Q3C Impurities: Guideline for Residual Solvents

USP General Chapter <467> Residual Solvents

Ph. Eur. Chapter 5.4 Residual Solvents

According to the above mentioned guidelines, residual solvents were evaluated for their possible risk to human health and placed into one of three classes as follows:

**Class 1 solvents:** Solvents to be avoided

Known human carcinogens, strongly suspected human carcinogens, and environmental hazards.

**Class 2 solvents:** Solvents to be limited

Non-genotoxic animal carcinogens or possible causative agents of other irreversible toxicity such as neurotoxicity or teratogenicity. Solvents suspected of other significant but reversible toxicities.

**Class 3 solvents:** Solvents with low toxic potential

Solvents with low toxic potential to humans; no health-based exposure limit is needed. Class 3 solvents have "permitted daily exposures" (PDE's) of 50 mg or more per day.

### Class 1 Solvents

Are class 1 solvents:

- used in the manufacture or purification of the Product
- likely to be produced during manufacture of the Product
- impurities of the starting materials used to manufacture the Product

Yes [ ] No [ X ]

Benzene		1,1-Dichloroethene	
Carbon tetrachloride		1,1,1-Trichloroethane	
1,2-Dichloroethane			

### Class 2 Solvents

**Are class 2 solvents:**

- **used in the manufacture or purification of the Product**
- **likely to be produced during manufacture of the Product**
- **impurities of the starting materials used to manufacture the Product**

**Yes**                                              **No**                                 

Acetonitrile		2-Methoxyethanol	
Chlorobenzene		Methylbutylketone	
Chloroform		Methylcyclohexane	
Cumene		Methylisobutylketone (acc. to ICH Q3C)	
Cyclohexane		Methylen chloride (acc. to USP)	
Cyclopentyl methyl ether (acc. to ICH Q3C)		N-Methylpyrrolidone	
1,2-Dichloroethane		Nitromethane	
Dichloromethane (acc. to ICH Q3C and Ph. Eur.)		Pyridine	
1,2-Dimethoxyethane		Sulfolane	
N,N-Dimethylacetamide		Tertiary-butyl alcohol (acc. to ICH Q3C)	
N,N-Dimethylformamide		Tetrahydrofuran	
1,4-Dioxane		Tetralin	
2-Ethoxyethanol		Toluene	
Ethylene glycol		1,1,2-Trichloroethene (acc. to ICH Q3C and Ph. Eur.)	
Formamide		Trichloroethylene (acc. to USP)	
Hexane		Xylene	
Methanol			

### Class 3 Solvents

**Are class 3 solvents:**

- **used in the manufacture or purification of the Product**
- **likely to be produced during manufacture of the Product**
- **impurities of the starting materials used to manufacture the Product**

**Yes**                                                                    **No**                                 

Acetic acid		Isobutyl acetate	
Acetone		Isopropyl acetate	

Anisole		Methyl acetate	
1-Butanol		3-Methyl-1-butanol	
2-Butanol		Methylethylketone	
Butyl acetate		Methylisobutylketone (acc. to Ph. Eur. and USP)	
tert-Butylmethyl ether		2-Methyl-1-propanol	
Dimethyl sulfoxide		2-Methyltetrahydrofuran (acc. to ICH Q3C)	
Ethanol		Pentane	
Ethyl acetate		1-Pentanol	
Ethyl ether		1-Propanol	
Ethyl formate		2-Propanol	<b>x</b>
Formic acid		Propyl acetate	
Heptane		Triethylamine (acc. to ICH Q3C)	

### Other Solvents

Are the following solvents [Solvents for which no adequate toxicological data was found]:

- used in the manufacture or purification of the Product
- likely to be produced during manufacture of the Product
- impurities of the starting materials used to manufacture the Product

Yes [ ] No [ X ]

1,1-Diethoxypropane		Methyltetrahydrofuran	
1,1-Dimethoxymethane		Petroleum ether (acc. to ICH Q3C and Ph. Eur.)	
2,2-Dimethoxypropane		Solvent hexane (acc. to USP)	
Isooctane		Trichloroacetic acid	
Isopropyl ether		Trifluoroacetic acid	
Methyl isopropyl ketone			

If any of the above mentioned solvents are likely to be present, please state the corresponding acceptance limit(s) in the Product as defined by your company.

Substance	Acceptance limit	JBL Specification
2-Propanol	≤ 500	mg/kg

**Comments**

The above mentioned product is manufactured by fermentation of carbohydrates. Except for the above mentioned 2-Propanol, the product does not get in to contact with solvents listed above.

As a class 3 solvent, 2-Propanol should be limited by GMP or other quality based requirements. As a consequence, the Jungbunzlauer acceptance limit of 2-Propanol in Xanthan Gum follows the strictest regulatory levels of max. 500 ppm.

Jungbunzlauer  
Technical Service