Residual Solvents

L(+)-Lactic Acid

Product name EC No.	L(+)-lactic acid 201-196-2 (general 200-018-0)	$C_3H_6O_3$
CAS No. E-No.	79-33-4 (general 50-21-5) E 270	

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

[X]

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-Dichloroethene	Nitromethane		
Dichloromethane (acc. to ICH Q3C and Ph. Eur.)	Pyridine		
1,2-Dimethoxyethane	Tertiary-butyl alcohol (acc. to ICH Q3C)		
N,N-Dimethylacetamide	Sulfolane		
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

[X]

Acetic acidIsobutyl acetateAcetoneIsopropyl 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	
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

Comments

The above mentioned product is manufactured by fermentation of carbohydrates. During its production process the product does not get into contact with solvents listed above.

Jungbunzlauer Technical Service