

Release Specification

Status	RS-BDDE 98%, Version 2
Syntagon's Product code	BDDE 98%
CAS Number	2425-79-8
Chemical name(s)	1,4-Butanediol diglycidyl ether; 1,4-Bis(2,3-epoxypropyloxy)butane
Molecular formula and weight	C ₁₀ H ₁₈ O ₄ , 202.25 g/mol
Retest interval	36 months from the date of initial purity analysis
Packaging	Primary: dark coloured borosilicate type 1 bottle. Teflon coated elastomeric material and blue capsule closure. Secondary: sealed transparent plastic bag.
Storage conditions	Room temperature

Test	Limit	Method (Testing laboratory)
Appearance (visual)	Colourless liquid	AM-General/Appearance, curr. ver. (Syntagon ¹)
Appearance of basic solution	Visually clear solution	AM-BDDE/ Appearance of solution, curr. ver. (Syntagon)
Identity (FT-IR)	Conforms to reference spectrum	Ph. Eur 2.2.24, curr. ver. (Syntagon)
Chromatographic purity (GC)		AM-BDDE/ BDDE 98% purity, curr. ver. (Syntagon)
Purity	≥ 98.0 %-area	
Sum of impurities (reporting threshold ≥ 0.01 %-area)	≤ 2.0 %-area	
Largest single impurity	≤ 1.0 %-area	
Chlorine content	≤ 0.1 % (w/w)	Quantitative ICP-MS (method L21, ALS Scandinavia)
Assay (titration)	97 - 103 % (w/w)	AM-BDDE/ Assay by titration, curr. ver. (Syntagon)
Residual solvents (HS-GC) Class 1, 2 and 3 solvents according to Table 1	According to Table 1	AM-BDDE/ Residual solvents USP, curr.ver. and AM-BDDE/ Residual Class 2 mixture C, pyridine, 1,4-dioxane, curr. ver. (Syntagon)

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Table 1. List of residual solvents

Class 1 Solvents	ICH limit (ppm)	Analytical method (1 or 2)^a
Benzene	< 2	1
Carbon tetrachloride	< 4	1
1,2-Dichloroethane	< 5	1
1,1-Dichloroethene	< 8	1
1,1,1-Trichloroethane	< 1500	1
Class 2 Solvents	ICH limit (ppm)	
Acetonitrile	< 410	1
Chlorobenzene	< 360	1
Chloroform	< 60	1
Cumene	< 70	1
Cyclohexane	< 3880	1
1,2-Dichloroethene	< 1870	1 (<i>trans</i> and <i>cis</i>)
1,2-Dimethoxyethane	< 100	1
N,N-Dimethylacetamide	< 1090	2
N,N-Dimethylformamide	< 880	2
1,4-Dioxane	< 380	2
Hexane	< 290	1
Methanol	< 3000	1
Methylbutylketone	< 50	1
Methylcyclohexane	< 1180	1
Methylene Chloride	< 600	1
Nitromethane	< 50	1
Pyridine	< 200	2
Tetrahydrofuran	< 720	1
Tetralin	< 100	1
Toluene	< 890	1
Trichloroethylene	< 80	1
m-Xylene	< 1302	1
o-Xylene	< 195	1
p-Xylene	< 304	1
Ethyl benzene	< 369	1
Class 3 Solvents	ICH limit (ppm)	
Ethanol	< 5000	1

^a Method 1. AM-BDDE/ Residual solvents USP, current version.

Method 2. AM-BDDE/ Residual Class 2 mixture C, pyridine, 1,4-dioxane, current version

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Status	June, 2018: Version 2: Appearance in solution has been specified to be in basic solution in addition to change of limit to "Visually clear solution". April, 2018: Version 1: - New document.
Remarks	¹ Testing laboratory "Syntagon" means that analysis may be carried out at Syntagon AB and affiliate laboratory Syntagon Baltic. Testing laboratory shall be specified on Certificate of Analysis. ² Specify size of packaging unit(s) on Certificate of Analysis. ³ Include BSE/TSE statement. ⁴ Include "latex free" statement.

Issued by Agnese Jurkevica, PhD
Site Manager

Date

Signature

Approved by Sofia Lofthagen, MSc
Quality Assurance Manager

Date

Signature