

Residual Statement

In the following we state, if according to our knowledge any substance(s) classified as 'Residual Solvent(s)' is/are used in the manufacture and/or purification of:

Product: BUTYL LACTATE NATURAL

- 1 None of the solvents classified 'Residual Solvents' in the Current USP <467> and the ICH Q3C guideline are used. The absence of such solvents as impurities in the above mentioned product is confirmed.
- 2 One or more of the solvents classified as **'Class 1 Residual Solvents'** in the Current USP <467>and the ICH Q3C guideline are used. The compliance of limited values of such solvents as impurities in the above mentioned product in accordance with the Current USP <467>and the ICH Q3C guideline is confirmed.
- 3 One or more of the solvents classified as **'Class 2 Residual Solvents'** in the Current USP <467>and the ICH Q3C guideline are used. The compliance of limited values of such solvents as impurities in the above mentioned product in accordance with the Current USP <467>and the ICH Q3C guideline is confirmed.
- 4 One or more of the solvents classified as **'Class 3 Residual Solvents'** in the Current USP <467>and the ICH Q3C guideline are used. The compliance of limited values of such solvents as impurities in the above mentioned product in accordance with the Current USP <467>and the ICH Q3C guideline is confirmed.
- 5 One or more of the solvents listed under **Table 4** in the Current USP <467>and the ICH Q3C guideline are used.

Solvent	Class	USP <467>and the ICH Q3C	Please fill this column Amount
		Specification Limit (ppm)	present in materials (ppm)
n.a	n.a	n.a	n.a

If 2, 3, 4 or 5 are applicable, please find the details in the table below:

-life D

Authorized Signature:

Name: Chelsea Chen

Title: Manager of Compliance and Regulatory Affairs Department Date: June 17, 2024