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Sodium Decanoate Impurity Analysis Summary

The following Sodium Decanoate (Sodium Caprate) samples were tested for organic impurity utilizing the currently validated BioSpectra GC MS instrumental method for organic impurity quantification. The impurity identification is based on the free acid impurity form as identified by mass spectrometry and retention time, for example, sodium caprylate (CAS 1984-06-1) impurity would be identified as the free acid octanoic acid.

Samples Analyzed:

- ND8201-006-0918
 - Raw Material lots used: ND3200-001-0718-PV, ND3200-002-0718-PV
- ND3220-004-1218
 - Bulk lot ND3200-012-1018
 - Raw Material lot used: KS20180725
- ND3201-005-0120
 - Bulk lot ND3200-030-0120
 - Raw Material lots used: ND3200-005-0818, ND8201-006-0918, ND8201-007-0918
- ND3201-007-0520
 - Bulk lot ND3200-031-0120
 - Raw Material lots used: KS20181114, ND8201-007-0918, ND3200-010-1018-PV, ND3200-011-1018-PV, ND3200-012-1018, NDE3200-013-1018, ND3200-014-1018
- NDEC-0121-00004
 - Bulk lot NDEC-0121-0133-PV
 - Raw Material lot used: KS20181114
- NDEC-0121-00005
 - Bulk lot NDEC-0121-00001-PV
 - Raw Material lot used: KS20181114

The analytical results are as follows:

¹ Lot ND8201-006-0918			
Sodium Octanoate Impurity (%)	Sodium Nonanoate Impurity (%)	Dodecanoic Acid Impurity (%)	Total Organic Impurity (%)
0.13	0.16	0.08	0.37

¹Sample was provided by Merck and Test Results were documented in MEMO19-725 and provided to Merck.

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¹Lot ND3220-004-1218			
Sodium Octanoate Impurity (%)	Sodium Nonanoate Impurity (%)	Dodecanoic Acid Impurity (%)	Total Organic Impurity (%)
0.14	0.17	0.09	0.40

¹Stability Sample was provided by Merck and Test Results were documented in MEMO19-725 and provided to Merck.

Lot ND3201-005-0120		
Sodium Octanoate Impurity (%)	Sodium Nonanoate Impurity (%)	Total Organic Impurity (%)
0.11	0.12	0.23

Lot ND3201-007-0520		
Sodium Octanoate Impurity (%)	Sodium Nonanoate Impurity (%)	Total Organic Impurity (%)
0.14	0.14	0.28

Lot NDEC-0121-00004			
Sodium Octanoate Impurity (%)	Sodium Nonanoate Impurity (%)	Impurity (%) detected at RRT of 1.1min	Total Organic Impurity (%)
None Detected	None Detected	0.12	<1.0

Lot NDEC-0121-00005			
Sodium Octanoate Impurity (%)	Sodium Nonanoate Impurity (%)	Impurity (%) detected at RRT of 1.1min	Total Organic Impurity (%)
None Detected	None Detected	0.12	<1.0

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