

## Frequently Asked Questions

- 1 What does SG (sensitive grade) mean?
  - Eastman 168 SG offers customers with sensitive applications, especially medical device OEMs, security of supply and the most stringent QA protocols in a high-purity product, coupled with access to proprietary ISO 10993 and USP Class VI test data. It offers low extractables, low migration, and a clean toxicological profile.
- 2 How is this different from the existing Eastman 168<sup>™</sup> non-phthalate plasticizer?
  - High product purity with stringent controls on residuals and impurities
  - · Access to proprietary test data
- 3 What does high product purity mean?
  - Specified low limit for DEHP
  - Specified low limit for 2-EH
  - Specified limit for trace heavy metals, including RoHS and EN71-3
- 4 Does Eastman 168 SG have stringent QA protocols?
  - cGMP compliant
  - Extensive procedures for lab testing, sample and records retention
  - · Customer auditing available
  - Traceability
- 5 What about security of supply?
  - · Extensive delivery and shipping practices
  - · Advanced notification of product or specification changes
- **6** What kind of test data is available?
  - · Access to ISO 10993 and USP Class VI test data
    - Biocompatibility data
  - · 2-generation reprotoxicity study
  - IV toxicity and migration

- 7 How does Eastman 168 SG compare to TOTM?
  - Lower cost
  - Higher efficiency
  - · Provides lower cost in use
- 8 Can Eastman 168 SG allow health care organizations to meet Environmentally Preferable Purchasing (EPP) guidelines?
  - · Yes.
- **9** Will my vendors be able to easily process Eastman 168 SG?
  - Yes. Eastman 168 SG does not require reformulation and may be a drop-in replacement for other plasticizers used in both sensitive and nonsensitive applications.
- 10 Can Eastman 168 SG be used for nonsensitive applications?
  - Yes. One of the benefits of Eastman 168 SG is that customers can use one plasticizer for all of their applications.
- 11 Is Eastman 168 SG compatible with existing sterilization methods?
  - Yes, it is compatible with sterilization methods including:
    - Autoclave
- Radiation (2.5 Mrad)
- Gas (EO)
- Gamma radiation

12 Where is Eastman 168 SG manufactured?

 Kingsport, Tenn., and Texas City, Texas, and is available globally



Contact your Eastman representative or compounder for additional information.



The results of **insight** 

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