

Solvents for headspace gas chromatography

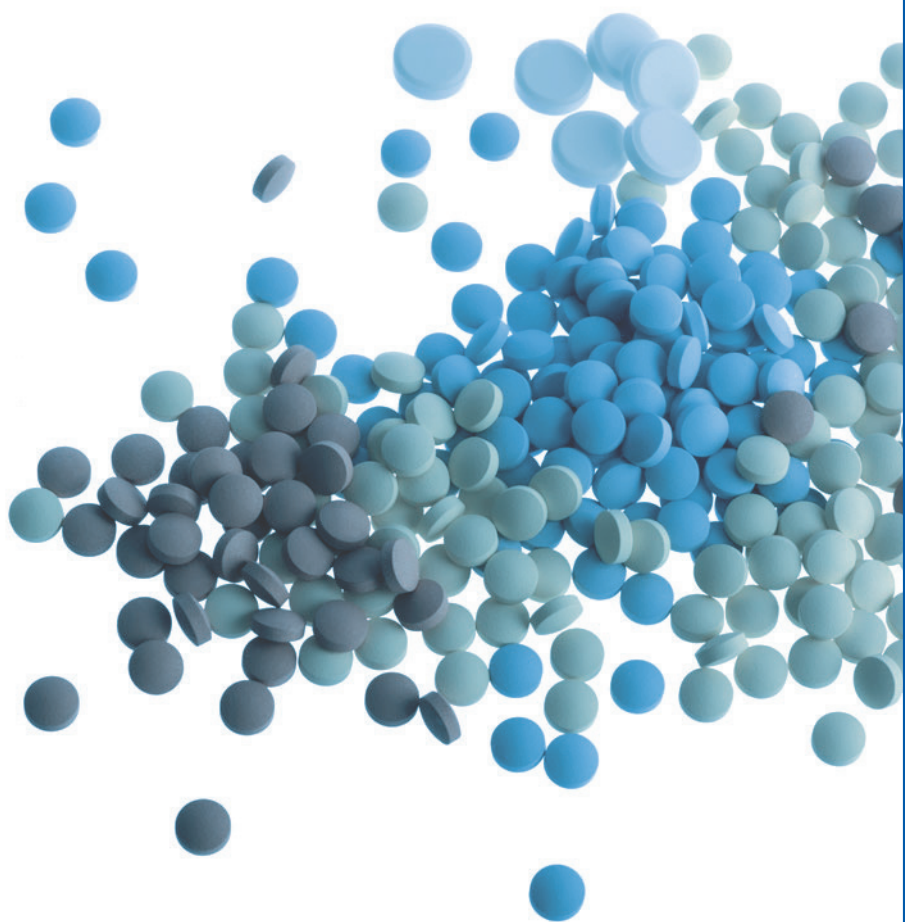
High purity for accurate, reliable and reproducible results

Headspace gas chromatography is a very precise and well accepted method for the analysis of residual solvents in drug substances and products in accordance with the ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use), USP and Ph Eur.

One challenge when working with headspace gas chromatography is to find a solvent quality that does not contain undefined levels of residual solvents, since this can interfere with the analysis. EMD Millipore has now introduced new SupraSolv® solvents especially designed to meet the sophisticated requirements of headspace gas chromatography: high purity and extremely low concentrations of residual solvents, as defined by the ICH.

Your benefits

- **High application reliability**
Due to the application test performed on every batch produced.
- **Application-oriented quality**
Due to specified concentrations of residual solvents as defined by the ICH.



Developed and specified in accordance with international standards

SupraSolv® solvents for headspace gas chromatography are optimized for the analysis of residual solvents in drug substances, excipients and drug products in accordance with ICH guideline Q3C "Impurities: Guideline for Residual Solvents". This guideline divides all residual solvents into three classes according to how harmful they are to human health, and defines permissible maximum concentrations in drug substances and products. Both the European Pharmacopeia (Chapter 2.4.24) and the United States Pharmacopeia (Chapter <467>) refer to this guideline.

Outstanding solvent quality

EMD Millipore offers application-oriented quality that helps you to achieve accurate and reliable analytical results every time.

For our headspace solvents, we specify precisely the concentrations of the various residual solvents defined in the ICH guideline. In addition, we perform a headspace application test for every batch produced. This gives you the application reliability you need for your daily work.

Find out more about solvents for headspace gas chromatography SupraSolv® on www.emdmillipore.com/solvents

Extract of specification

Every residual solvent of class 1 acc. ICH	≤ 1 µg/g
Every residual solvent of class 2 acc. ICH	≤ 10 µg/g
Every residual solvent of class 3 acc. ICH	≤ 50 µg/g

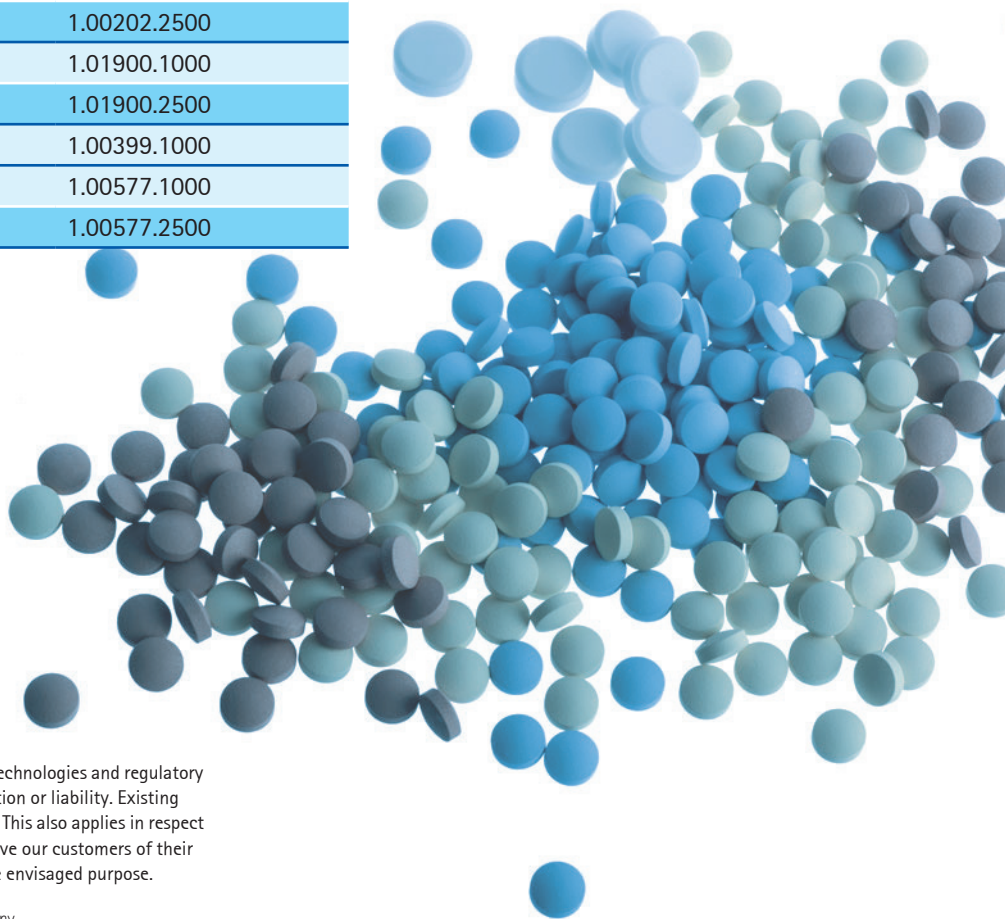
ICH = International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

SupraSolv® Headspace

For the analysis of residual solvents according to Ph Eur and USP

Product	Content Packaging	Order No.
N,N-Dimethylformamide	1 l GL	1.00202.1000
	2.5 l GL	1.00202.2500
Dimethyl sulfoxide	1 l GL	1.01900.1000
	2.5 l GL	1.01900.2500
N,N-Dimethylacetamide	1 l GL	1.00399.1000
Water	1 l GL	1.00577.1000
	2.5 l GL	1.00577.2500

GL = glass bottle



We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

EMD Millipore and the M logo are trademarks of Merck KGaA, Darmstadt, Germany.

© 2012 EMD Millipore Corporation, Billerica, MA USA. All rights reserved.

LE SBU-12-07630 11/2012 Printed in the USA.