

Strasbourg, 17/07/2015

Terms and conditions for EDQM safety documentation and their use

The EDQM protects public health with **quality standards for safe medicines** and their safe use. See [EDQM Vision, Mission & Values](#) for more information. The use of chemicals of high concern is avoided in these quality standards; notably in the European Pharmacopoeia monographs. In the interest of patient health, the EDQM supplies chemicals that, in some cases, may be of very high concern. They are for scientific research, analysis and development¹ only and are not intended for human or animal consumption.

To ensure regulatory compliance as a downstream user, the EDQM has classified chemicals in accordance with Regulation (EC) No 1272/2008 and supplies hazardous chemicals with safety data sheets (SDS) in accordance with article 31 and annex II of Regulation (EC) No 1907/2006, as amended.

Terms and conditions

Under no circumstances should the EDQM SDS be used to determine any characteristics of the chemicals other than those intended by UNECE TDG and GHS, as enacted in the EU.

In no event shall the Council of Europe (EDQM) be liable for any lost profits, loss of use, costs of procurement of substitute goods or systems, or for any indirect, special, incidental, punitive, or consequential damages, however caused and, whether in contract, tort or under any other theory of liability.

In no event shall the Council of Europe (EDQM) be liable for any damage caused by the use of the SDS outside their scope.

In accordance with the Ph. Eur. General notices 10000: "CAS registry numbers are included for information, where applicable, to provide convenient access to useful information for users. CAS Registry Number® is a registered trademark of the American Chemical Society".

As far as possible, the EDQM aligns the SDS information with the relevant monograph and not with batches, unless it affects the hazard classification. For example, different hydration degrees and, consequently, different CAS numbers alone do not justify an SDS revision. The SDS do not replace monographs, leaflets, summary of product characteristics (SmPC), periodic safety update reports (PSUR), etc.

- The EDQM obtains classification data primarily from EC/ECHA/EMA, OECD, WHO etc. and, if not available, from suppliers. The EDQM Secretariat carries out verification to ensure consistency. With the exception of classification taken from annexes to Regulations (EC) No 1272/2008 and (EC) No 1907/2006, the EDQM considers the authorities of member states have not verified the classifications.

¹ As defined in article 3(23) of Regulation (EC) No 1907/2006 and article 2(30) of Regulation (EC) No 1272/2008, and fulfilling the conditions of Annex I to Regulation (EU) No 487/2013 paragraph 1.5.2.4.1.

- Most impurities do not have safety data and, under these circumstances, they should be considered at least as hazardous as the chemicals they are related to.
- The EDQM can provide SDS in the official languages of the Council of Europe, i.e. English and French. For hazardous chemicals, SDS in some other member state languages can also be provided, but the translated versions have not been verified.
- Compliance with any national requirements is not guaranteed and remains the responsibility of downstream users.
- The EDQM has carried out risk assessments in the EDQM setting, but only for the applicable quantities (usually in mg) and intended uses (quality control laboratory). This provides the basis for the exposure prevention recommendations of section 8 of SDS. Downstream users are responsible for assessing the risks of any uses of the products in their own settings. ***The EDQM SDS information is not applicable to large-scale use (industrial).***
- The EDQM does not issue SDS for harmless materials (e.g. herbals, cotton wool) unless new data arises or an amendment to the legislation later justifies chemical classification.

Any other interpretation and use is the sole responsibility of users.