

Product Origin Information & FAQ

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1. General Information

This document describes details and provides guidance on Origin Declarations offered for products of the Life Science (LS) business of Merck (MilliporeSigma in the US and Canada).

Such Quality Declarations are issued upon customer, business or authority request and are primarily used for our customers' product-specific risk assessment. Customer requests for origin information include country of manufacturing origin and geographical source of animal origin raw materials (when applicable). Different processes and rules apply. This document refers to the material origin.

This information is provided for informational use only. The customer is responsible for ensuring the products are suitable for their intended use.

2. Why are different document types provided for origin information?

Merck is a global company with a variety of product portfolio offerings. Different portfolios have different regulatory needs and risk profiles. While adhering to the highest standards and meeting or exceeding the applicable regulatory requirements, we are also balancing data acquisition costs in a global supply chain with product availability and price. In our continuous endeavor to provide a harmonized face to our customer for ease of business and risk assessment, we will continue to harmonize the layout, content and wording of our origin statements while keeping in mind customer needs and regulatory requirements.

2.1 What origin information types are available?

Depending on the portfolio the origin information is requested for, one of the following three statement types contains the origin information.

- Certificate of Origin (CofO)
- Animal Origin Declaration (AO)
- Origin Declaration with TSE/BSE statement

3. What does origin information stand for?

Depending on the portfolio and the provided origin information statement, different origins of the requested product can be listed. Please find more detail on the origin information below.

3.1 Biologic Origin

A product derived from a process involving animal (including human), plant or fermentative origin.

3.2. Animal Origin

A product derived from a process involving animal (including human) raw materials.

3.3 Fermentative Origin

The product is produced directly by microbial fermentation. Fermentation is defined by chemical reactions carried out by living microbial organisms.

3.4 Mineral Origin

The product originates from a mined source.

3.5 Natural Origin

The product is produced by nature; non-living sources e.g. salts, minerals, crude oil fractions.

3.6 Synthetic Origin

A product which is chemically produced by synthetic production steps.

3.7 Vegetable Origin (VO)

The product is obtained directly from vegetable material e.g. physical or chemical extraction.

4. For which products is origin information available?

Various types of information are available based on product group and application. In general, the provision of Certificates of Origin (CofO) or Animal Origin (AO) information are not part of the M-Clarity promise.

By default, (Animal) Origin information containing a BSE/TSE statement are available for products in Merck Quality (MQ) Level of MQ400 - MQ600. For products allocated in MQ100 - MQ300, (Animal) Origin information may be available upon request, if the material qualification allows for it and the information is available.

Details on how to request origin information can be found in section 7.

More information about the M-Clarity program can be found on the M-Clarity program webpages: [Millipore](#) or [Sigma-Aldrich](#)

5. What is the purpose for CofO / AO / TSE/BSE?

The primary purpose of providing information about the origin, especially the animal / biological origin is to create a basis for a risk assessment as demanded by Regulatory agencies and Pharmacopeias respectively. Therefore, animal material and such which is additionally modified by chemical, physical or biological production steps, while retaining its basic organic form are considered.

Additionally, religious concerns like Halal, may depend to a certain extent on the biological source. Besides this statement also supports our customers in their wish to reduce products delivered from animal origin.

Lastly, veterinary agencies have imposed controls on the handling, import and export of materials from animal / biological origins, for which certain information

may be required, for instance, species, country of biological origin and any treatments (i.e., material processing, equipment sterilization).

6. What is the risk of TSE/BSE?

Products of animal, including human, Origin can pose biological risks regardless of the species. Ruminants in particular, which often serve as a source of animal raw materials, carry the risk of transmissible spongiform encephalopathy (TSE).

The neurodegenerative diseases are caused by a Prion. This Prion is an infectious protein without DNA or RNA, therefore not being a living organism. The host precursor of this infectious protein is a non-infectious agent, which is present in all animal species (including man). While transmission mechanisms of this Prion (within a single species or from one species to another species) are not well known, the transmission minimization of those Prions through pharmaceutical products is a major concern, since the presence of Prions is not easily demonstrated with a diagnostic test and Prions adhere very tenaciously to surfaces. Besides, Prions are very stable and are not destroyed by sterilization processes. Therefore, customers might be concerned about products of possible Animal Origin used in the manufacturing process or coming into contact with the product in question.

Minimizing this risk is the aim of the relevant EMA Guideline for the manufacture of products intended for use in medicinal products for human and veterinary use (Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 current Revision)). This set of rules categorizes animal tissue and materials based on risk, right up to "non-TSE relevant" materials. Such risks can be avoided through sourcing and manufacturing process.

To support our customer with the needed information, LS is collecting information from our suppliers and internal manufacturing sites to provide verified source and manufacturing information.

This collected information will undertake a risk assessment and the final outcome will be presented in an Origin document type as given in section 3. Depending on the quality level, as well as the portfolio the product belongs to, the level of details given in the Origin document type may vary.

6.1 Do we offer BSE/TSE statements?

Yes, certain portfolios and MQ-Level products are covered with an Origin Declaration including TSE/BSE statement (see also section 3). Depending on the quality level, as well as the portfolio the product belongs to, the level of details given in the Origin document type may vary.

7. How can origin information be requested?

7.1 Self-Service for SAFC products

7.1.1 Self-Service for EMPROVE products

- 1) In case the product is an EMPROVE brand (is part of the product name), please follow the steps given below:
- 2) Go to <https://www.merckmillipore.com/>
- 3) Enter product number in search field

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100013

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- 4) Choose "Material Qualification Dossier" of the selected product and download the dossier, containing Origin Declaration via your SUITE access OR choose "Certificates" and download the document directly.

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Search All 100013

61 Results for "100013"

Showing: Products (9), Documents (52), Site Content (0)

Narrow Your Results

Products by Type

- Test Methods and Kits (3)
- Standards and Reference Materials (3)
- Test Strips (1)

Products by Application

100013 SAFAC Acetone

EMPROVE® ESSENTIAL Ph Eur,BP,JPE,NF

More Information

Show Pricing & Availability

Quality Management Dossier

Operational Excellence Dossier

SDS

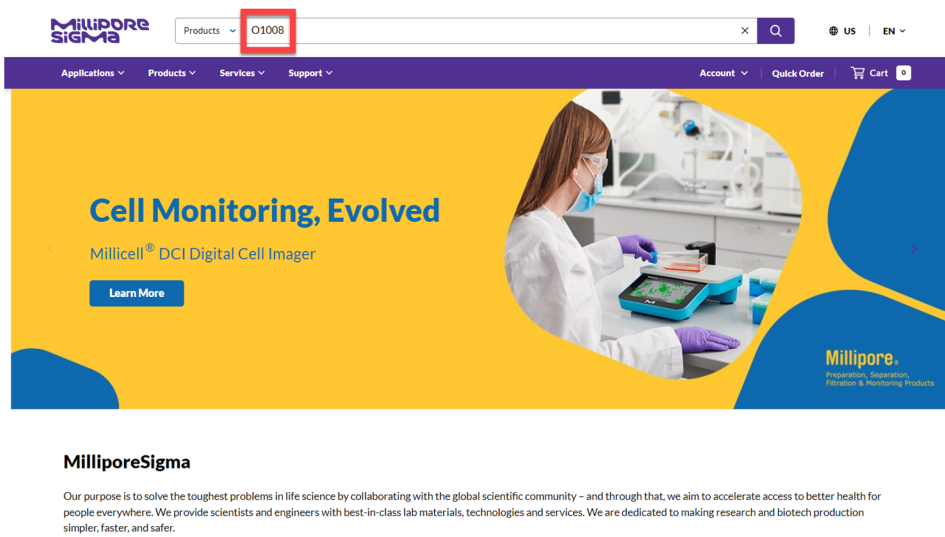
Certificates

Material Qualification Dossier

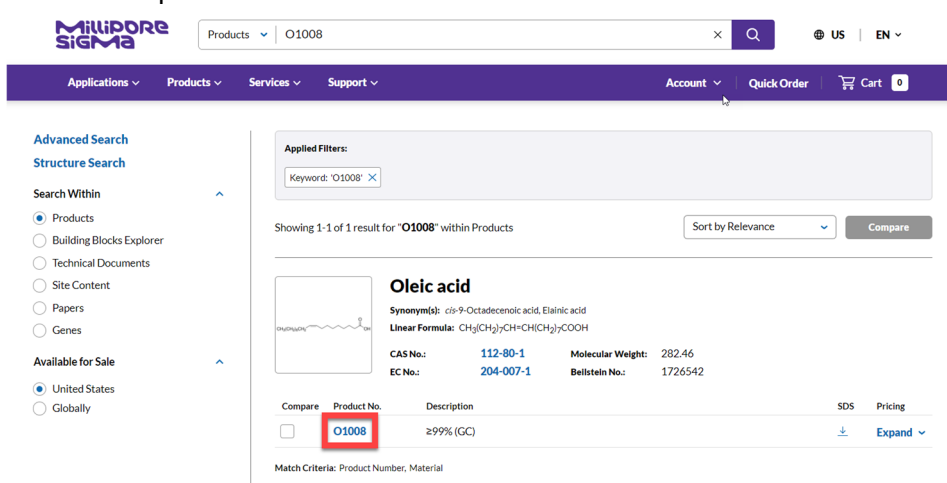
- a. In case you are no SUITE customer yet and want to purchase access, please subscribe via the homepage or contact your service partner for support.

7.2 Self-Service for Sigma-Aldrich products

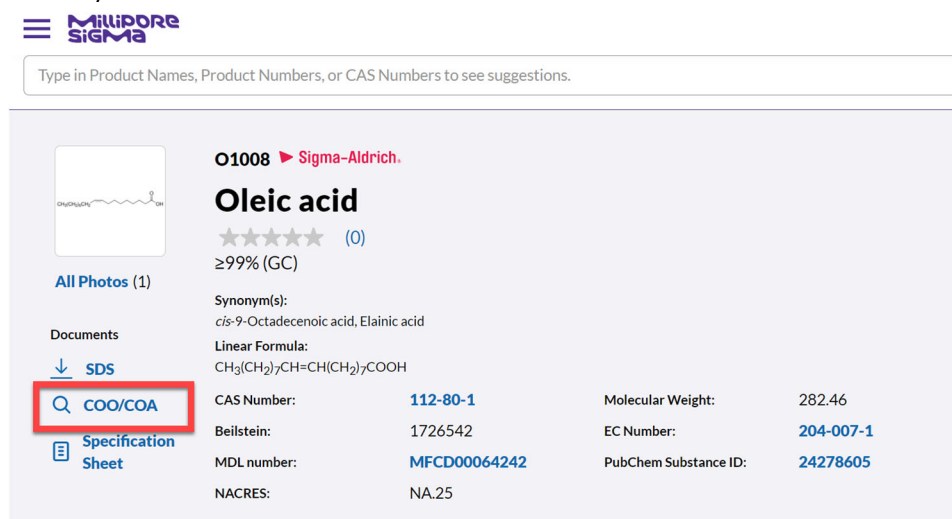
- 1) In case the product is a Sigma-Aldrich product, please go to <http://www.sigmaaldrich.com>
- 2) Enter product number in the search field



3) Choose the product



4) Select COO/COA



5) Enter lot number of the product

DOCUMENTATION

Certificate of Analysis | [View Sample COA](#)

Lot Number
e.g. 023J5431

[How to enter Lot Number \(COA\)](#)

Certificate of Origin

Lot Number
SLBX1935

[How to enter Lot Number \(COO\)](#)

More Documents

[Spectra - ATR-IR](#) [Structure Search](#)

[Pressure-Temperature Nomograph](#)

[Bulk Quote-Order Product](#)

- If CoFo is available: The document can be directly downloaded
- If CoFo is not available: Request CoFo via the automatically displayed form

7.3 Other products

In case Origin information can't be obtained as described above, please contact your responsible 1st Level Support (Commercial Service, Tech Service, Sales Support).