



Industrial Merchant

STATEMENT

Absence of Phthalates in the PHARGALIS⁽¹⁾ products

We, Air Liquide Benelux Industries – Industrial Merchant Activity, represented by Mrs Ann Diels Product Quality & Metrology Manager - Compliance Officer,

State the following:

- Phthalates are chemical substances used to soften PVC articles (type of plastic often part of the composition of medical equipment).
- Certain phthalates are proven toxic and classified as “CMR” substances or “carcinogenic, mutagenic or toxic for reproduction”. The related Directive 2007/47/CE⁽²⁾ defines obligations for the medical equipment manufacturers using CMR classified phthalates (categories 1 and 2 according to the Annex I of the Directive 67/548/CE⁽²⁾).
- Given the nature of the raw materials and the employed production means, the Air Liquide pharmaceutical gases sold under the Phargalis brand, in both bulk and cylinder supply, are not and do not contain any phthalates. Therefore the PHARGALIS gases can be used in the production of active pharmaceutical principles or drugs, with respect to the mentioned Directives.

This statement is valid until July 2018. It can be renewed upon request.

City/Site: Brussels

Date: 15/07/2015

Ann Diels
Product Quality & Metrology Manager - Compliance Officer

(1) The PHARGALIS offer includes the following products: PHARGALIS 1, PHARGALIS 2, PHARGALIS 3

(2) Reference legal texts:

- DIRECTIVE 2007/47/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market
- Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.