



Industrial Merchant

STATEMENT

Absence of Allergens 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:

- Air Liquide pharmaceutical gases commercialized under the PHARGALIS brand, in both bulk and cylinder supply, are not submitted to the European Directive 2000/13/CE ⁽²⁾, which applies exclusively to “foodstuff destined to be delivered as-is to final consumers, as well as to restaurants, hospitals, canteens and other similar collectivities” (First article, paragraphs 1 and 2 of the Directive 2001/13/CE).
- Nevertheless, given their nature, the raw materials and the employed production processes are exempt of any allergen substance, as defined by the Directives 2003/89/CE ⁽²⁾ et 2006/142/CE ⁽²⁾.
- Therefore, the PHARGALIS gases can be used in the production of active pharmaceutical principles or drugs, with respect to the 3 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) References legal texts:

- Directive 2000/13/CE regarding the labelling, presentation and advertising of foodstuffs
- Directive 2003/89/EC of the European Parliament and of the Council of 10 November 2003 amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs (Text with EEA relevance)
- Directive 2006/142/CE amending Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council listing the ingredients which must under all circumstances appear on the labelling of foodstuffs