



Industrie Plastiche Lombarde S.p.A.

Sede Sociale e Uffici

Via L. da Vinci, 13c - 21023 Besozzo (VA) - Italy
Tel. 0332/770252 - Telefax 0332/970792
sito internet <http://www.ipl.it>

C.C.I.A.A. di Varese n. 137571 - M. VA006166
Registro Società n 10140 Tribunale di Varese
Capitale Sociale Euro 625.000
Codice Fiscale e Partita IVA 00413650128

Da(From): **IPL**
Tel: **+39 0332 770252**
Fax: **+39 0332 971456**

A (To): **GUMEX, spol. s r.o.**
Za Drahou 1856,
696 62 Strážnice

Arianna BIO [B1 01] Plutone Bio [B2 01] Plutone Press BIO [B3 01]

The above-mentioned hose (identification code B1 01, B2 01 and B3 01) is manufactured by Industrie Plastiche Lombarde SpA in the site of Besozzo - Italy, and by IPL SCHLAUCHTECHNIK GmbH in the site of Voelkermarkt - Austria according to the following normative and regulations:

EU

- Commission Regulation (EU) No. 10/2011 of 14 January 2011 on Plastics Materials and articles intended to come in contact with foods, CE Regulation n° 1935/2004, and following updating.
- Commission Regulation (EU) No. 2023/2006 of 22 December 2006 on the Good Manufacturing Practices.

The above-mentioned hoses can be used for transfer of foodstuffs for which tests with the following simulants are required:

- A (moist food products with pH > 4.5 and food products containing alcohol up to 10% v/v)
- B (acid food products with pH < 4.5)
- C (food products containing alcohol up to 20% v/v)

The articles contain substances which are subject to a restriction :

- CAS 8013-07-8 Epoxidized Soya Bean Oil (ESBO)
- CAS 736150-63-3 Glycerides, castor-oil mono-, hydrogenated, acetates
- CAS 75-01-4 Vinyl chloride monomer
- CAS 103-23-1 Di-2-ethylexyl adipate (DEHA)
- CAS 2082-79-3 Octadecyl 3-(3,5-di-Tert-butyl-4-hydroxyphenyl) propionate-
- CAS 7128-64-5 2,5-Bis(5-tert-butyl-benzoxazol-2-yl)thiophene
- CAS 2440-22-4 2-(2-Hydroxy-5-methylphenyl)benzotriazole
- CAS 6422-86-2 DOTP
- CAS // Zinc, salts
- CAS // Calcium salts of fatty acid (DUAL USE art. 11 3a)

The articles are in compliance with the overall migration limits and specific restrictions, evaluated under the in the following conditions:

- Simulants B (acetic acid 3%) and C (ethanol 20%)
- Time and temperature of testing: 10 days/40°C
- Ratio of food contact surface area to volume in the range $2 \div 0,5 \text{ cm}^2/\text{cm}^3$

We inform you that results from our last migration tests (global and specific migration) are all lower than the quantification limit.

USA

- FDA-CFR 21 parts 170 to 199 Item 175.300, for food passage
- Testing with simulators in compliance with condition of use D and G.

We inform you that the above-mentioned articles are manufactured with raw materials that do not contain, intentionally added, any of the plasticizers that belong to the orthophthalates group.

We want to call your attention to the fact that, according to the law, the final user is responsible to check the technological suitability of the hoses referred to the purpose for which it is assigned.

This document refers only to the food-contact and pharma Regulatory of the hose. Concerning all other characteristics of the hose (working performance, service temperature etc) our catalogue should be used as reference or it is possible to contact our customer office.

Emitted by:
Giancarlo Tarantini
Lab R&D