



versalis

Direzione e Uffici Amministrativi

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San Donato Milanese, 24/11/2020

Snetor

Re: PHARMALENE MR50 PH / MS40 PH.

As per your request, we can confirm that in the production of our materials in ref., the metals listed in the ICH Guideline for elemental Impurities Q3D step 5 (2019) and Q3C (R5) on impurities guideline for residual solvents, are not used.

From the foregoing, we can confirm that there is no reason that said substances may be found in the a.m. materials as supplied in original packaging.

We cannot exclude the presence of negligible traces of the elements listed in the guideline below concern limits. The end user has to ascertain that their final article complies to the expected requirements.

We confirm that our mentioned products comply with the requirements of Regulation 1272/2008/EC and following amendments on "Classification, packaging and labelling of substances and mixture" and with the restrictions set by the REACH Regulation 1907/2006/EC, annex XVII "Restrictions on the manufacture, placing on the market and use of certain substances and articles" and following amendments.

These laws remains our regulatory reference in case of claims.

Yours sincerely

Product Compliance Mgr.
Salvatore Minardi

Versalis spa

Sede Legale: San Donato Milanese (MI) - Piazza Boldrini, 1 - Italia
Capitale sociale interamente versato: Euro 1.364.790.000,00
Codice Fiscale e Registro Imprese di Milano-Monza-Brianza-Lodi 03823300821
Part. IVA IT 01768800748
R.E.A. Milano n. 1351279
Società soggetta all'attività di direzione e coordinamento di Eni S.p.A.
Società con socio unico