Version: February 23, 2023

PHARMACOPOEIA DECLARATION

It is the responsibility of our customers to check if the materials supplied by SABIC and articles made out of it are suitable for the intended use and comply with all applicable regulations and requirements.

Europe

SABIC® LDPE PCG80 - 00900 complies with the compositional requirements of Monograph 3.1.3. “Polyolefins” and Monograph 3.1.4. “Polyethylene without additives for containers for preparations for parenteral use and for ophthalmic preparations” of the European Pharmacopoeia (Edition 11.2).

Tests carried out with raw material granules have shown that **SABIC® LDPE PCG80 - 00900** complies with the requirements of Monograph 3.1.4. “Polyethylene without additives for parenteral preparations and ophthalmic preparations” of the European Pharmacopoeia.

USA

SABIC® LDPE PCG80 - 00900 passed the relevant physicochemical tests according to USP <661.1> and in vivo biological reactivity tests required for the USP <88> Class VI requirements.
It complies with Plastic Class VI 70°C-24h requirements

It has to be recognized that these tests have been carried out with the raw material as such. The final responsibility for the decision whether a material is fit for a certain application lies with the responsible pharmacist of the pharmaceutical firm.

ISO 10993

ISO standard 10993 contains specific tests that have to be carried out on the medical device (the final article). SABIC is only producing plastic intermediate materials in granule form) and on top of that a compounding step will be necessary to convert our material into the final article (the medical device). This processing step is outside the responsibility of SABIC.
Therefore, it is SABIC's opinion that the results of ISO standard 10993 tests carried out on SABIC® PCG materials would have only a very relative value and therefore offer no guarantees for compliance of the final article (the medical device).

SABIC has not carried out tests according to the requirements of ISO standard 10993 on **SABIC® LDPE PCG80 - 00900**.

As mentioned before, in vivo biological reactivity tests carried out on **SABIC® LDPE PCG80 - 00900** have shown, that this material complies with the requirements of Plastic Class VI 70°C-24h according to USP <88> Class VI.

Without going too much into detail, there are some similarities between USP <88> Class VI and ISO standard 10993. USP <88> Class VI contains:

- a systemic injection test, which is also described in ISO 10993-11:2018 (Tests for systemic toxicity)
- an intracutaneous injection test, which is also described in ISO 10993-10:2013 (Tests for irritation and sensitization) and
- a muscle implantation, which is also described in ISO 10993-6:2017 (Tests for local effects after implantation).

Please note that minor difference can apply between the USP <88> Class VI and the indicated ISO 10993 sub-standards.

This declaration applies to the material as it leaves its production facilities. It does not cover any substance(s) or preparation(s) subsequently added and/or inexpert material processing or article fabrication further down in the supply chain.

Please note carefully that Regulations develop continuously and that SABIC declarations may be adapted accordingly. This declaration replaces all previous versions relating to this subject and product and will, unless revoked in writing, be valid for a period of 1 (one) year, after which it will automatically expire.

If you have any further questions, or require any additional information on the above, please use the *"Contact Us"* form on the SABIC website. After selecting the option "Products" and your product, choose *"Regulatory"* as option under *"What is the nature of your inquiry"*.
The form is available via https://www.sabic.com/en/contact.

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