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Precision made in Germany

27. June 2023

REACH
Restriction on the manufacture, placing on the market and use of PFASs
- E.2.9. Medical devices: Per- and polyfluoroalkyl substances (PFAS) -

In January 2023, five European authorities (Denmark, Germany, the Netherlands, Norway and Sweden) submitted a proposal for restrictions to the European Chemicals Agency (ECHA). They collaborated on this proposal to restrict the manufacture, use and placing on the market of per- and polyfluorinated substances (PFASs) in the EU. The submitted dossier justifies the restriction that PFASs are difficult to degrade in the environment and therefore remain in the environment for a very long time. Some PFAS can accumulate in animals, plants and humans and are also considered harmful to health.

PFASs are a group of several thousand individual compounds with different molecular structures and diverse physical, chemical, and biological properties. Therefore, the diversity and toxicological profile of such substances should be properly recognized and adequately addressed.

However, we are concerned that a general restriction on PFAS will have a significant impact on eye care patients in the European Union. Implantable per- and polyfluorinated compounds (PFAS) have been used for the treatment of severe retinal diseases since the 90s of the 20th century. Inadequate treatment of the diseases leads in all cases to a significant deterioration of visual performance and mostly to irreversible blindness of the patient. After using these products on humans as intraocular endotamponades, the product residues are disposed of by thermal incineration as is customary and prescribed in hospitals and medical practices.

The mode of action of these medical devices is based on a higher density than water and air. Chemical inertness is also essential to prevent inflammatory reactions in the eye, which are very difficult and painful for the patient to treat. Both high density and chemical inertness are achieved by incorporating fluorine atoms into the chemical structure of the medical devices. The fluorine cannot be replaced by any other non-radioactive atom. Therefore, a substitute for the products as implantable tamponade in the ophthalmic field is not possible in the future. A pending manufacturing restriction means a significant deterioration of the treatment success.

Therefore, the Geuder AG demands that certain PFASs suitable for intraocular use must be exempted from any restrictions for the benefit of patients.

Geuder AG (www.geuder.de) has been developing and manufacturing innovative medical devices for retinal and cataract surgery for over 40 years. In this field, Geuder AG plays a worldwide leading role in providing ophthalmic surgeons with creative and efficient solutions. The company's competence focuses on the development, manufacture, and marketing authorization of active medical devices, instruments and light and heavy tamponades for retinal surgery, perfluorohydrocarbons and semifluorinated alkanes as temporary tamponades, as well as dyes for anterior and posterior segment surgery.

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Medical devices affected by the pending restriction:

Product group:	**Densiron®**
Trade name medical devices:	**Densiron® 68; Densiron® Xtra**
Composition:	**Densiron® 68:** **30,5% perfluorohexyloctane ($C_6F_{13}C_8H_{17}$)** **69,5% polydimethylsiloxane, 5000 cSt ($(C_2H_6OSi)_n$)** **Densiron® Xtra:** **30,5% perfluorohexyloctane ($C_6F_{13}C_8H_{17}$)** **69,5% polydimethylsiloxane, 4200 cSt ($(C_2H_6OSi)_n$)**
Indication:	Densiron® 68/Densiron® Xtra are intended only for ocular application. Densiron® 68/Densiron® Xtra are used for the treatment of severe cases of retinal detachment, including in particular: • Inferior and posterior retinal holes • Retinal detachments with giant tears • Retinal detachments with proliferative vitreoretinopathy (PVR) • Traumatic retinal detachments. Densiron® 68 and Densiron® Xtra are also used as a tamponade in macular hole surgery.
Product group:	**PFCL**
Trade name medical devices:	**F-Octane; F-Decalin**
Composition:	**F-Octane:** **100% perfluorooctane (C_8F_{18})** **F-Decalin:** **100% perfluorodecalin ($C_{10}F_{18}$)**
Indication:	F-Octane/F-Decalin are intended only for ocular application. F-Octane/F-Decalin are used in particular for: • Unfolding detached retinas • Giant tears • Traumas • Floating dislocated lenses
Trade name medical device:	**F4H5® WashOut**
Composition:	**100% perfluorobutylpentane ($C_9H_{11}F_9$)**
Indication:	F4H5® WashOut is used in ophthalmic surgery for removal of silicone oil residues. • for the removal of silicone oil residues from the retina • for cleaning intraocular lenses following silicone oil tamponade
Product group:	**EasyGas®**
Trade name medical devices:	**EasyGas® C_2F_6; EasyGas® C_3F_8**
Composition:	**EasyGas® C_2F_6: 16% hexafluoroethane (C_2F_6)** **84% synthetic air** **EasyGas® C_3F_8: 12% octafluoropropane (C_3F_8)** **88% synthetic air**
Indication:	EasyGas® C_2F_6/C_3F_8 are intended only for ocular application. EasyGas® C_2F_6/C_3F_8 are used following surgical treatment of macular holes. In addition, EasyGas® C_2F_6/C_3F_8 are used in corneal grafting and as a long-term tamponade following surgical treatment of severe retinal detachments, especially in cases of: • Retinal detachments with giant tears • Retinal detachments without proliferation • Retinal detachments with proliferative vitreoretinopathy • Retinal detachments in cases of proliferative diabetic retinopathy • Traumatic retinal detachments

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