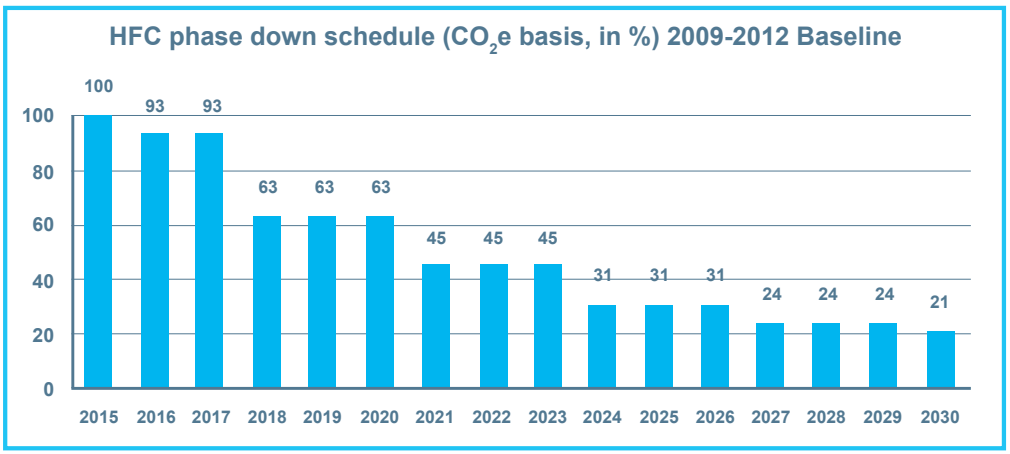
The Impact of the Key Global and National HFC Regulations on Zephex® Medical Propellants

Mexichem is the world leader in the manufacture and supply of very high purity HFA medical propellants and as a business plays an important role in meeting the demands of regulation. Such regulations will ultimately have a big impact on the choice of propellants used in aerosol products with a GWP of 150 or more, except when used for medical applications. This document provides guidance on how these new regulations impact on Zephex® Medical Propellants.

EU F-Gas Regulations (EU 517/2014)

The 2014 EU F-Gas regulation seeks to minimise the global warming caused by emissions of Hydrofluorocarbons (HFCs) through a quota system that will phase down the quantity of HFCs placed on the EU market.



This affects all HFC use including Hydrofluoralkanes (HFA's) used in Metered Dose Inhalers (MDIs). Under the regulation, both Mexichem (as the HFA producer/importer) and the MDI manufacturer have compliance obligations.

Zephex® 134a and Zephex® 227ea are classed as HFCs under the regulation.

The supply of Zephex® is included within an exemption from the phase down quota requirement as from 1st January 2018. However, the full phase down quota requirement, does apply for all Zephex® sales during 2015-2017.

What does this actually mean for Zephex®?

All sales of Zephex® within the European Union between 1st January 2015 and 1st January 2018 must be included within Mexichem's quota allocation. To enable Mexichem to manage their quota allocation during this period it is imperative that customers agree their requirements in good time as failure to do so could result in supplies of Zephex® being restricted.

Mexichem can partially exempt Zephex® sales in the European Union from their quota allocation from the 1st January 2018, if both Mexichem and the customer comply fully with the rules of the regulation (see below).

There are a number of key steps that must be undertaken by the Producer/Importer (Mexichem) and Customer (MDI Manufacturer) to ensure that the use of Zephex® in the production of MDIs in the European Union complies with the new regulation.

Mexichem®
Medical Propellants

Key steps to ensure compliance:

Mexichem, will

- Undertake the required registration, reporting and quota management activities to ensure that it always maintains the ability to supply Zephex® to customers that require the product
- Certify that the production of Zephex® products conform to the requirements of the regulation
- Ensure that all Zephex® transactions are reported correctly to the European Commission and can be correctly accounted for in the phase down quota system
- Comply with all necessary labelling requirements for Zephex® packages supplied to the MDI manufacturers

EU manufacturers of MDIs will need to

- Register with the European Commission (Article 17 (1) d))
- Confirm the use of Zephex® supplied
- Ensure that they operate their storage and filling processes to minimise all HFC emissions (Article 3 (1))

US EPA Significant New Alternatives Policy (SNAP)

The US EPA continues to update their list of alternatives to Ozone Depleting Substances (SNAP); this list includes the acceptable use of HFAs as Medical Propellants. In 2015, the US EPA confirmed that the continued use of Zephex® 134a and Zephex® 227ea is acceptable in FDA-approved MDIs for medical purposes.

Montreal Protocol HFC Phase down (Kigali Amendment)

The Kigali amendment will phase down, not phase out, the use of HFCs on a GWP weighed basis. The use of HFAs in MDIs is currently included within the Global HFC phasedown under this amendment, however current levels of HFA use in MDIs suggests that the phase down will not affect the availability of HFA medical propellants in the foreseeable future.

Mexichem expertise

Mexichem has been involved in the development of the various regulations and amendments. Therefore, Mexichem has the expertise to help and provide advice to MDI manufacturers in understanding the regulations and will work with its customers to ensure compliance and minimise any impact.

For further information on our products or concerns over usage please contact your local Mexichem representative who will be more than willing to help you.

For more information please contact:

www.zephex.com