ZEPHEX®

HFA Medical Propellants

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Pure quality

We are the world leader in the manufacture and supply of very high purity HFA medical propellants. Produced to the most demanding industry standards at dedicated facilities, Zephex® propellants are used in over 80% of the world's metered dose inhalers.

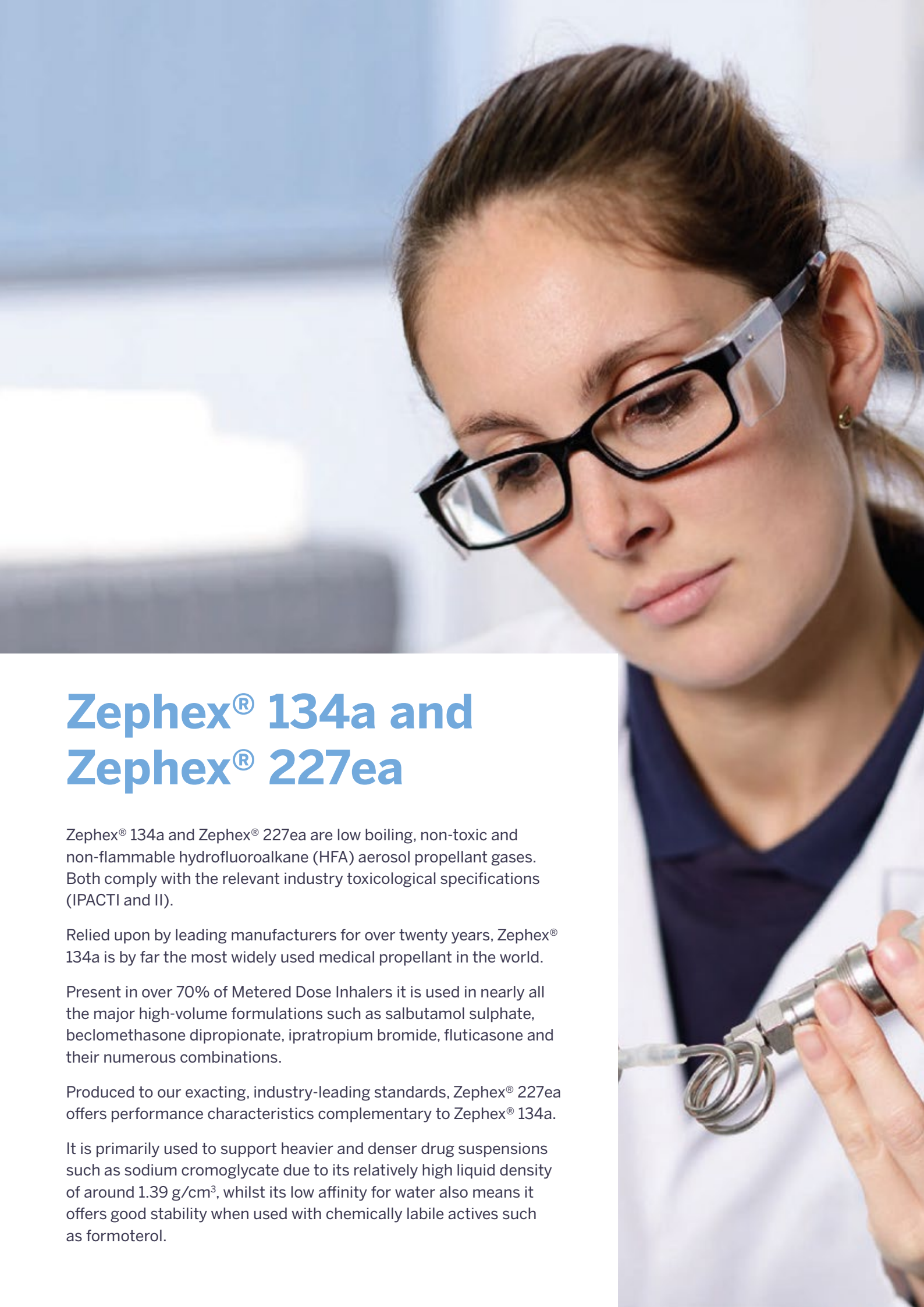
This commitment to the highest levels of medical propellant quality is supported by a detailed understanding of customer requirements and experienced staff with many years of technical expertise.

Leading the world in manufacturing best practice

Our state-of-the-art manufacturing facilities have been designed and constructed to stringent current Good Manufacturing Practice (cGMP) standards.

The Zephex® facility in Cheshire, UK is the only one of its kind to have received an FDA audit, as well as inspections by the UK Medicines and Healthcare Products Regulatory Agency (MHRA), ensuring we remain at the leading edge of industry cGMP compliance.

Zephex® 134a analytical techniques have been confirmed to be equivalent if not better than those described in the Norflurane European Pharmacopeia (EP) Monograph. Zephex® 134a meets the requirement of our more stringent Mexichem specification and the requirements of IPACT1.



Zephex® 134a and Zephex® 227ea

Zephex® 134a and Zephex® 227ea are low boiling, non-toxic and non-flammable hydrofluoroalkane (HFA) aerosol propellant gases. Both comply with the relevant industry toxicological specifications (IPACTI and II).

Relied upon by leading manufacturers for over twenty years, Zephex® 134a is by far the most widely used medical propellant in the world.

Present in over 70% of Metered Dose Inhalers it is used in nearly all the major high-volume formulations such as salbutamol sulphate, beclomethasone dipropionate, ipratropium bromide, fluticasone and their numerous combinations.

Produced to our exacting, industry-leading standards, Zephex® 227ea offers performance characteristics complementary to Zephex® 134a.

It is primarily used to support heavier and denser drug suspensions such as sodium cromoglycate due to its relatively high liquid density of around 1.39 g/cm^3, whilst its low affinity for water also means it offers good stability when used with chemically labile actives such as formoterol.

Product specifics

Zephex® 134a			
Property		Units	Value
Molecular Weight			102.03
Boiling Point	(1atm)	°C	-26.1
Melting Point		°C	-103.0
Critical Temperature		°C	101.0
Critical Pressure		bara	40.56
Critical Volume		m^3/kg	1.97×10^{-3}
Critical Density		kg/m^3	507.6
Saturated Vapour Density at nBPt		kg/m^3	5.26
Vapour Pressure	(25°C)	bara	6.652
Latent Heat of Evaporation at nBPt			216.8
Coefficient of Thermal Expansion	(LIQ, 0-20°C)	/°C	0.002766
Solubility of HFA 134a in Water	(20°C/1atm)	% w/w	0.0773
Solubility of Water in HFA 134a	(25°C/1atm)	% w/w	0.11
Flammability in Air (1atm)			None
Autoignition temperature		°C	770
Liquid dielectric constant	(25°C)		9.51
Vapour dielectric constant	(25°C/1 atm)		1.014
Dielectric strength	(R12=1)		0.5
Dipole moment			2.06

Zephex® 227ea			
Property		Units	Value
Molecular Weight			170.03
Boiling Point	(1 atm)	°C	-16.5
Melting Point		°C	-131.2
Critical Temperature		°C	102.8
Critical Pressure		bara	2987.74
Critical Volume		m^3/kg	1.72×10^{-3}
Critical Density		kg/m^3	581.4
Saturated Vapour Density at nBPt		kg/m^3	35.94
Vapour Pressure	(25°C)	bara	4.544
Latent Heat of Evaporation at nBPt			132.02
Coefficient of Thermal Expansion	(LIQ, 0-20°C)	/°C	Not yet available
Solubility of HFA 227ea in Water	(20°C/1atm)	% w/w	0.058
Solubility of Water in HFA 227ea	(25°C/1atm)	% w/w	0.061
Flammability in Air (1atm)			None
Autoignition temperature		°C	>650
Liquid dielectric constant	(20°C)		4.071
Vapour dielectric constant	(25°C/1atm)		Not yet available
Dielectric strength	(R12=I)		Not yet available
Dipole moment			1.456 ±0.002

Quality guaranteed

Zephex® propellants are manufactured at industry leading facilities where all products are subject to a comprehensive quality control process involving eleven separate tests to confirm purity and quality.

Dedicated stainless steel containers are used for the supply of Zephex® at manufacturing scale, eliminating problems associated with conventional packaging common to the rest of the industry.

A number of steps are taken to ensure the quality of each package we supply, including security tagging with a unique number recorded on the Certificate of Analysis. This certificate contains a hologram mark to assure customers they are receiving only pure Zephex® quality.

Dedicated customer support

The highly experienced Zephex® team provide a comprehensive range of key support services to customers as an integral part of our offering, including:

- In addition to our own Certificate of Analysis, if required we can facilitate completely independent customer "acceptance testing" to analyse shipments before they are despatched
- Support in complying with ICH guidelines as confirmed by inspection bodies such as the FDA and MHRA, and in meeting other legislation such as the European F-Gas regulations
- Skilled analytical and transport engineering services to assist in the specification, design, installation and validation of propellant storage and handling facilities
- A range of technical support including formulation advice, full regulatory documentation support and analytical methods

Simon Gardner

Medical Products General Manager

Our team can tailor support services to suit individual requirements, please contact zephexsales@kouraglobal.com

Fit for the Future

Our production and distribution capabilities for Zephex® 134a and Zephex® 227ea mean customers are sure of excellent security of supply for both products.

Mexichem is committed to continuing investment in the medical propellants sector to maintain its industry leading standard in manufacturing and customer support. We are always ready to support customers' experimental programmes and can supply propellants for this purpose.

Please contact us on the details below to discuss further.

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