

To: Whom it may concern

The relationship between ICI Klea, INEOS Fluor, Mexichem UK Ltd, Mexichem UK Ltd trading as Mexichem Fluor and Koura Global

ZEPHEX® medical products were initially developed and marketed by Imperial Chemical Industries (ICI) in the early 1990s. ICI was one of the most significant global chemical manufacturers at that time. The name 'Klea®' was the brand name for refrigerant products produced at the time and remains so today.

INEOS Fluor was formed on 9 January 2001 when Imperial Chemical Industries ('ICI') divested its Fluorochemicals business ('ICI Klea') to the INEOS Group. With operations in the United Kingdom, the United States and Japan this sale complied with laws and regulations applicable to such transfers of business assets within these three jurisdictions. The Drug Master File for 1,1,1,2-tetrafluoroethane (ZEPHEX® 134a) which had been filed with the US FDA transferred from ICI Klea to INEOS Fluor at the time of divestment.

On 31 March 2010 the business and assets of INEOS Fluor were sold to Mexichem Fluor S.A. de CV. With operations in the United Kingdom, the United States and Japan this sale complied with all laws and regulations applicable to such transfers of business assets within these three jurisdictions. The Drug Master Files for 1,1,1,2-tetrafluoroethane (ZEPHEX® 134a) and Heptafluoropropane (ZEPHEX® 227ea) were transferred to Mexichem UK Ltd (trading as Mexichem Fluor), at the time of the sale of the business assets.

On 5 September 2019 the Mexichem global business undertook a rebranding exercise. The global business became 'Orbia' and the business was restructured into five 'business streams', one of which was Mexichem UK Ltd. Mexichem UK Ltd (trading as Mexichem Fluor) was re-branded as 'Koura Global'. Although the rebranding is now in progress, Mexichem UK Ltd remains the trading legal entity until further notice.

On behalf of Koura Global, trading as Mexichem UK Ltd.,

A handwritten signature in blue ink, appearing to be "C. R. Dodd", written over a horizontal line.

Christopher R Dodd
Medical Regulatory Manager
11 February 2020