

TO WHOM IT CONCERNS

STATEMENT REGARDING SAFETY DATA SHEETS

Wound Care and First Aid products supplied by Orkla under the brands Cederroth First Aid and Salvequick/Salvelox are classified as Medical Devices in accordance with the directive 93/42/EEC and the Medical Device Regulation 2017/745. Most of these products are not substances or mixtures, so the requirements for providing Safety Data Sheets do not apply.

According to Article 6 of the REACH Regulation 1907/2006, mixtures that are Medical devices are exempted from the requirement of providing Safety Data Sheets, provided that the same level of protection is ensured by compliance to other legislation, in this case the Medical Device Directive 93/42/EEC or Medical Device Regulation 2017/745.

Therefore, for the majority of Orkla's Wound Care and First Aid products, Safety Data Sheets are not required.

Exception:

For products that contain a pressurized container, Safety Data Sheets are required for transport purposes.

This currently applies for

REF 51011005	Burn Gel 100ml
REF 726000	Eye&Wound Cleanser Spray
REF 51030002	Wound Cleanser Spray

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