

To whom It May Concern,

Salts Healthcare Ltd has made a reasonable review of the manufacturing components, processes and supportive documentation and states that to the best of its knowledge the products listed below comply with the following statement.

“The requirements to provide an SDS arise from Article 31 of the REACH Regulation. Certain general exemptions from the need to supply information according to Title IV (therefore including SDSs according to Article 31) are given in Article 2 (6). This includes medical devices which are mixtures in the finished state, intended for the final user. REACH also does not require that SDS to be provided for articles”.

The Salts Healthcare Ostomy Devices and Accessories listed below are Medical Devices, intended for the final user and in most cases for direct contact with human body. Also, products listed below are considered ‘Articles’ ‘as per REACH Article 3(3).

Additionally, none of the concerned products contain ‘substances of very high concern’ (SVHCs).

None of Salts Healthcare Ostomy products incorporate declarable substances relating to substances that are subject to authorization for use and exemptions as per REACH Annex XIV.

Ostomy products do not contain declarable substances relating to restrictions on the use of certain dangerous substances and preparations in accordance with Annex XVII – Restricted Substances List.

Salts Healthcare Ostomy products, as medical devices, do not fall under Regulation (EC)1272/2008 (CLP Regulation). Additionally, none of the concerned products contain CMR substances that would be classified as such according to Annex VI Part 3 of CLP Regulation.

In addition, Salts Healthcare Ltd products do not incorporate any nanomaterials or substances with endocrine-disrupting properties as defined by Regulation (EU) 2017/745 (MDR) Annex I Chapter II.

Taking into account above assessment, Salts Healthcare Ltd states that Safety Data Sheet is not required and has not been issued for the below products:

Product name	Product codes
Confidence Be Adjustable Belts	BB01ST, BB01B, BB01W
Salts Adjustable Belts	AB01, AB02
Night Drainage Bag	ZL0400
Confidence Be Night Drainage Bag	BNDB
Night Drainage Adaptor	NDA6
Salts Support Wear	Refer to DoC 63*
Confidence Comfort Pouches	Refer to DoC 62*
Harmony Duo	Refer to DoC 66*
Confidence Natural Pouches	Refer to DoC 70*

\*Available on request.

Kind regards

Yours sincerely



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Quality & Regulatory Senior Manager