ConvaTec Global Development Centre, First Avenue, Deeside Industrial Park, Deeside, Flintshire CH5 2NU
Tel: +44 (0) 1244 584333. Fax: +44 (0) 1244 584311
www.convatec.com

9th March 2016

To whom it may concern,

Requests for Safety Data Sheets:

The United States Occupational Safety and Health Administration (OSHA) now requires Hazardous Chemical reporting be done via a uniform Safety Data Sheet (SDS) rather than the previously used Material Safety Data Sheet (MSDS). OSHA has standardized the Hazard Communication Standard (HCS) in order to better align with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) now being implemented worldwide. SDSs are documents that travel with or ahead of hazardous chemical shipments, warning users of the specific dangers of such products and guidance on their safe handling, storage and disposal.

Medical devices are exempt from OSHA rules [see 29 CFR 1910.1200(c)] with the Food, Drugs and Cosmetic (FD&C) Act and Title 21 of the Code of Federal Regulations (21CFR) taking precedence. Specifically, medical devices are considered to be "articles" as defined by the HCS, therefore not requiring an SDS. Products manufactured or fabricated into an "article" are typically whole units that do not and cannot pose a risk in that they cannot be ingested, inhaled, or absorbed into the body. However, medical device labelling is equally stringent and the relevant warnings must be clearly displayed on all levels of packaging and in the accompanying *Package Insert* or *Instructions for Use* documentation.

The majority of ConvaTec products are registered as medical devices and consequently do not have SDS. However, for a very limited number of products SDS have been prepared and can be supplied upon request. For Over the Counter (OTC) drug products conforming to FDA monographs, cosmetic products and products containing flammable components or compressed gas, SDS are provided. Simple mechanical equipment such as fixing brackets do not require SDS.

SDSs are not designed for individual end-users to identify individual components or for detailed formula information; this is beyond the intended scope of SDS documents.

Sincerely,

David Parsons PhD, MRSC CChem
Director of Science and Technology
ConvaTec Research and Development