Medtronic supplies the following product(s) that meets the definition of an article under the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS), the European Union (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Standard, United States (US) Occupational Health and Safety Administration (OSHA) Hazard Communication Standard, Canadian Workplace Hazardous Materials Information System (WHMIS) Regulation, and Australian Work Health and Safety (WHS) Regulation. Therefore, under normal usage of this product(s), a Safety Data Sheet (SDS) is not required for the product(s) listed below.

6560-6560 PREPPIES-SKN BARRIER WIPE

The UN GHS includes an exemption for articles, which is defined as a manufactured item:

(i) which is formed to a specific shape or design during manufacture;
(ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and
(iii) which, under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical, and does not pose a physical or health risk to employees.

GHS has incorporated by reference the US OSHA article definition for the exemption.

Additionally, the EU REACH, US OSHA Hazard Communication Standard, Canadian WHMIS Regulation and the Australian Regulation on the Classification of Hazardous Substances all contain a similar exclusion for manufactured articles. Further, these articles are not considered dangerous substances or mixtures and are outside of the scope of the EU Classification, Labeling and Packaging (CLP) Regulation.

Please feel free to contact Medtronic if you require any further information.