

Labelling and Expiration Dates

maxill customers have asked us about the absence of expiry / expiration dates on certain labeled packaging. Expiry dating legally applies to certain classes of products and not for others. For these other products, expiry dating is optional; a determination made by the manufacturer.

This discussion will help to clear up a lot of confusion that is “out there.” The following information applies to the products sold by maxill.

PRODUCTS LABELED WITH EXPIRY DATES

There are only two classes of products that are legally obligated to carry expiry dates on labeling.

1. Natural Health Products that are labeled with a Natural Product Number (NPN)

<https://laws-lois.justice.gc.ca/eng/regulations/sor-2003-196/page-6.html#h-700957>

75 (1)(c) The sponsor shall ensure that the natural health product bears a label that sets out the following information in both official languages: The expiry date of the natural health product.

2. Drugs that are labeled with a Drug Identification Number (DIN)

https://laws-lois.justice.gc.ca/eng/Regulations/C.R.C.,_c._870/page-62.html#docCont

C.01.004 (1)(c)(v) The inner and outer labels of a drug shall show on any panel the expiration date of the drug.

PRODUCTS LABELED WITH EXPIRY DATES, AS AN OPTION

There are three other classes of products are not legally obligated to set out expiry dates on labeling.

1. Cosmetics

https://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._869/page-1.html#h-567479

Neither Sections 17 to 24 (Labeling) nor the whole set of regulations include any of the following terms: expiry, expiration, “best before”, “use by” or “shelf life.” A manufacturer of cosmetics may choose to display an expiry, “use by” or “best before” date if it deems there is a projected shelf life that is determined by any known point in time beyond the date of manufacture, when degradation in product quality or packaging renders a product unfit for use.

2. Medical Devices

With respect to expiry dating on a label, only the following applicable reference is written in the Regulations

<https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-2.html#h-1021458>

21(1)(g) No person shall import or sell a medical device unless the device has a label that sets out the following information: the expiry date of the device, if the device has one, to be determined by the manufacturer on the basis of the component that has the shortest projected useful life.

“Projected useful life” is mentioned only five other times in the regulations, none of which are within the context to obligations with respect to labeling.

Unfortunately, Section 21(1)(g) is vague and applies to all medical devices. Manufacturers may choose to set out on their label an expiry date at their discretion.

Class I and Class II devices often do not have expiry dates on labels due to the design simplicity and inherent longevity of life of many devices in these classes (e.g. toothbrush, dental scaler, cotton rolls, etc.). The manufacturer may have on record a recommended “best before” date, often greater than three years beyond the date of manufacture.

Class III and Class IV devices will often always have expiry dates, due to their higher risk class. Health Canada may ask the manufacturer to conduct shelf-life studies in order to obtain their medical device licence. In addition, the label may need to set out an expiry date.

3. General Merchandise (not NPN, DIN, Cosmetic nor Medical Device)

With respect to general merchandise like general purpose cleaners and laboratory supplies, manufacturers may choose to set out an expiry date on their label at its discretion; if it deems there is a projected shelf life that is determined by any known point in time beyond the date of manufacture, when degradation in product quality or packaging renders a product unfit for use. Regardless, there is no obligation for the manufacturer to set out an expiry date on the label.

For further reading on legal obligations to product safety:

Consumer Chemicals and Containers Regulations, 2001

<https://laws-lois.justice.gc.ca/eng/regulations/SOR-2015-17/FullText.html>

Hazardous Products Regulations

<https://laws-lois.justice.gc.ca/eng/regulations/sor-2001-269/FullText.html>