

LIFE CYCLE INVENTORY ANALYSIS

Data collection procedure

Primary data were collected for all operations under Novartis' direct control. In addition, primary data were sourced from the manufacturer of the digital companion. For sites not under Novartis's control, utilities data were difficult to obtain and approximations based on similar processes controlled by Novartis were used. For materials, the data sources were mainly technical activity data and bills of materials. Energy data for API and Inhaler production were received directly from Novartis owned sites.

Secondary sourced data were used for the background system or where the relative impact on the footprint result is nominal.

LCI data: device and digital companion manufacturing and distribution

Primary data provided by Novartis included the following:

- Bills of materials for: inhaler devices (including excipients) and inhaler packaging;
- Site energy, fuel use and production volumes for inhaler production and packing based on Novartis supplied data; and
- Supply chain maps.

In addition, primary data were sourced from the digital companion manufacturer and include:

- Bills of materials for the digital companion device and its packaging; and
- Supply map.

Utilities data were estimated for the digital companion device, based on Novartis' inhaler production energies. A non-disclosure agreement was signed with the manufacturer, with the understanding that no information about the bill of materials is available to the commissioner of this study.

The bills of materials for the inhaler devices have been split into: device materials and utilities; and excipients and packaging. These are presented in the following tables.

Table 1 Device materials – per device

Component	Inhaler device	
	Quantity	Unit
<i>Inhaler device</i>		
ABS plastic (acrylonitrile butadiene styrene)	12.9	g
Stainless steel	2.30	g
mABS (methylmethacrylate acrylonitrile butadiene styrene)	1.30	g
<i>Digital companion device – Details not disclosed</i>		

Table 2 Utilities for manufacturing – per device

Component	Inhaler device	
	Quantity	Unit
Electricity	0.14	kWh
Natural gas	5.49*10 ⁻⁵	MJ

Table 3 Excipients – per capsule

Component	Quantity	Unit
HPMC capsule shell	48.0	mg
Lactose monohydrate	24.5	mg

Note: there is some variation in the mass of capsule and its composition depending on the APIs included ($\pm 2\%$)

Table 4 Packaging materials – per device

Component	30-day packs		90-day packs	
	Quantity	Unit	Quantity	Unit
<i>Weight to pack 1 Inhaler device</i>				
Paper cardboard	25.0	g	29.3	g
Paper tray	12.0	g	13.8	g
Paper leaflet	17.0	g	19.6	g
<i>Weight for blister packs</i>	3 blister packs containing 30 capsules		9 blister packs containing 90 capsules	
PVC (part of blister foil)	1.74	g	5.22	g
Aluminium multi-laminate (part of blister foil)	3.66	g	11.0	g

Table 5 Packaging materials – per digital companion device

Component	Annual package	
	Quantity	Unit
<i>Weight to pack 1 digital companion device</i>		
Paper cardboard	12.0	g
Paper tray	7.0	g
Paper leaflet	7.0	g

Secondary data

Secondary data for emission factors come from ecoinvent 3.6 ¹.

Assumptions

A number of assumptions were made in this streamlined study.

- **Digital companion assembly energy:** digital companion assembly energy consumption was estimated to be 60% of that associated with the inhaler assembly itself, based on the relative mass of the two products (excluding digital companion battery). The utilities data for the inhaler assembly were obtained directly from Novartis.

Table 6 Utilities for assembly – per digital companion

Component	Digital companion	
	Quantity	Unit
Digital companion		
Electricity	0.04	kWh
Natural gas	$1.65 \cdot 10^{-5}$	MJ

- **End of life (EoL):** The split of waste management routes for the inhaler device itself can be found in Table , using data provided by Novartis.

¹ <https://www.ecoinvent.org/database/older-versions/ecoinvent-35/ecoinvent-35.html>

Table 7 End of life disposal – statistical share

	% incineration with energy recovery	% incineration without energy recovery	% landfill
France	60	40	0
Germany	100	0	0
UK	80	0	20
Japan	60	40	0

- **Transport distances:** these were estimated by using actual distances between the respective production locations, which are: Stein, Switzerland; Osnago, Italy; and Barbera, Spain. A 20 km distance was assumed from waste collection to end of life management in each market and a 10 km distance was assumed for transport of waste from API production sites to a waste management facility.

Allocation

The inhaler production site produces more than one type of product. Consequently, allocation was required for the energy data collected. The annual 2019 energy data provided by Novartis were allocated to products, based on the total 2019 output of the site in stock keeping units (SKU). Total 2019 production volumes for the stock of all products and utilities data were provided for the site. The energy data were then allocated to each inhaler by dividing the total energy data by total number of units (of all products) produced by the factory.

The impact of distribution was determined based on mass. Data on the location of each site were provided and distances between the sites were calculated (using PortWorld and Google Maps). The total mass of each packaged product at each transport stage was calculated and was then multiplied by the distance travelled to produce a figure in

'kg.km'. This figure was then used in SimaPro to model the total footprint of the distribution life cycle stage.

The recycled content approach is employed for the recycling of materials and recovery of energy at end-of-life. The recycled content method applies to the allocation of impacts from the processing of waste materials in order that they can be used in another process (ie recycling/reuse/energy recovery). This method allocates 100% of impacts incurred from recycling processes (eg cleaning, sorting, chipping etc.) to the system that uses the recycled material or recovered energy. This method was applied to all materials that were recycled or have energy recovered from them at end of life.