

Influence of Geography on the Carbon Footprint Impact of Breezhaler® Dry Powder Inhaler

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Summary

Inhalers have a significant contribution to the carbon footprint (CFP) of healthcare. Novartis is committed to reduce the environmental impact of its product and in line with this commitment, the Breezhaler® device is available as a hydrofluoroalkane/chlorofluorocarbon-free dry powder inhaler for delivery of asthma medications.

This paper presents the findings of the cradle-to-grave CFP studies of two Breezhaler® inhaled combinations (indacaterol acetate/mometasone furoate [IND/MF] and IND/glycopyrronium bromide/MF [IND/GLY/MF]) from Italy and Spain; additionally, a conservative estimate, which can be used as a reliable proxy for CFP of Breezhaler® in other countries, is also reported. The Breezhaler® combinations assessed were IND/MF (30-day pack, without digital companion), IND/GLY/MF (30-day packs, with and without digital companion) and IND/GLY/MF (90-day pack, without digital companion).

The Breezhaler® combination of IND/GLY/MF (without digital companion) has the lowest CFP among all the combinations evaluated. Similar CFP estimates were reported for all the Breezhaler® portfolio products in the most conservative estimate and the countries evaluated.

Active pharmaceutical ingredients, inhaler production energy and packaging are the main contributors to the CFP; for IND/GLY/MF, 30-day pack with digital companion, the raw materials of the digital companion have the highest contribution. Excipients, distribution, and end-of-life stages all make minimal contributions to the CFP of Breezhaler® products.

Overall, the low CFP of the Breezhaler® portfolio (which has fixed dose combinations of IND/MF and IND/GLY/MF) is not influenced by geography and the findings from Italy, Spain and the conservative estimates are all consistent with the published literature from other countries.

Key Message

The Breezhaler® portfolio (which has fixed dose combinations of IND/MF and IND/GLY/MF) has a low carbon footprint (CFP) across the world. Even at the most conservative estimate, the CFP of Breezhaler® is low and consistent with footprints of countries evaluated in this study (Italy and Spain) and in previous studies (France, Germany, Japan, and UK).

Introduction

The “cradle-to-grave” analysis technique assesses the environmental impact associated with all stages (raw material extraction to processing, manufacturing, distribution, use, and disposal) of a product’s life [1]. This assessment has the objective of understanding the influence of geography on the CFP of the Breezhaler® products with respect to the underlying goals of identifying hotspots in the product life cycle and potential opportunities to reduce its products impacts.

Two combinations (indacaterol acetate/mometasone furoate [IND/MF] and IND/glycopyrronium bromide/MF [IND/GLY/MF]) were assessed in three product formats: 30-day pack without digital companion, 30-day pack with digital companion and 90-day pack without digital companion. The digital companion refers to a sensor attached to the Breezhaler® device and the accompanying mobile application which provides inhalation confirmation, medication reminders and access to objective data on clinical condition and sensor-related information to better support therapeutic decisions.

Main Body of Text

Methods

Data were modelled using Ecoinvent 3.6 database on the SimaPro LCA software version 9.1.0.82, and the impact of each product has been calculated using the Intergovernmental Panel on Climate Change impact assessment method with a timeframe of 100 years (IPCC 2013 GWP 100a). The CFP studies

comply with the methodological requirements set out in the Greenhouse Gas Protocol Product Life Cycle Accounting and Reporting Standard, (GHG protocol).

The functional unit (FU) is defined as: “An inhaler device used for 30-days to treat a patient differentiated according to the characteristics of Italy or Spain or in the most conservative scenario.” As the 90-day pack is analysed for 30-days of use (i.e., employing the same FU as the 30-day packs), the FU for the 90-day pack includes one-third of the inhaler and one-third of the 90-day capsule pack. When a digital companion is used, the FU contains one-twelfth of a digital companion and its respective packaging.

The most conservative scenario represents the longest possible distribution distance and assumes that all wastes are incinerated without energy recovery. This is expected to have the highest carbon footprint (CFP) at all life stages because combustion releases greenhouse gas emissions without counterbalancing the benefits of avoiding other sources of energy. The most conservative estimate can be used as a reliable proxy for CFP of Breezhaler® products in countries where cradle-to-grave studies have not been conducted.

Included in this analysis were API synthesis, capsule/inhaler/digital companion production, packaging and distribution, energy used at the pharmacy during storage, the use of the inhaler by patients and the disposal of the Breezhaler® device, digital companion, and packaging. The manufacture, maintenance and disposal of machinery required during the manufacturing process, as well as the manufacture and upkeep of buildings, are all excluded from the scope of the study.

Results

The results of the CFP assessment (per day, per month, and per year) for each of the evaluated Breezhaler® products, done via the cradle-to-grave analysis, are shown in **Table 1**. The difference between the most conservative estimate and the findings from countries is less than 10%, indicating that the CFP of the Breezhaler® devices in all parts of the world will be consistent with the CFPs from Italy and Spain. Impacts for one month have been calculated on a 30-day basis, with one year taken to be 365 days. The breakdown of the CFP by life cycle stage in geographies is shown in **Figure 1**.

A cradle-to-gate CFP was also conducted which refers to the footprint of each inhaler device from resource extraction to the factory gate, omitting the distribution, use and end-of-life of the product. IND/GLY/MF (90-day) has the lowest cradle-to-gate CFP of 0.194 kg CO₂eq per month, while the 30-day IND/GLY/MF device with digital companion has the highest at 0.490 kg CO₂eq per month.

Additionally, a gate-to-gate CFP analysis, including the emissions directly from Novartis controlled sites and those associated with energy used at Novartis controlled sites, was done. IND/GLY/MF (90-day) has the lowest gate-to-gate CFP of 0.041 kg CO₂ eq per month, while the IND/MF device with digital companion showed the highest at 0.115 kg CO₂ eq per month.

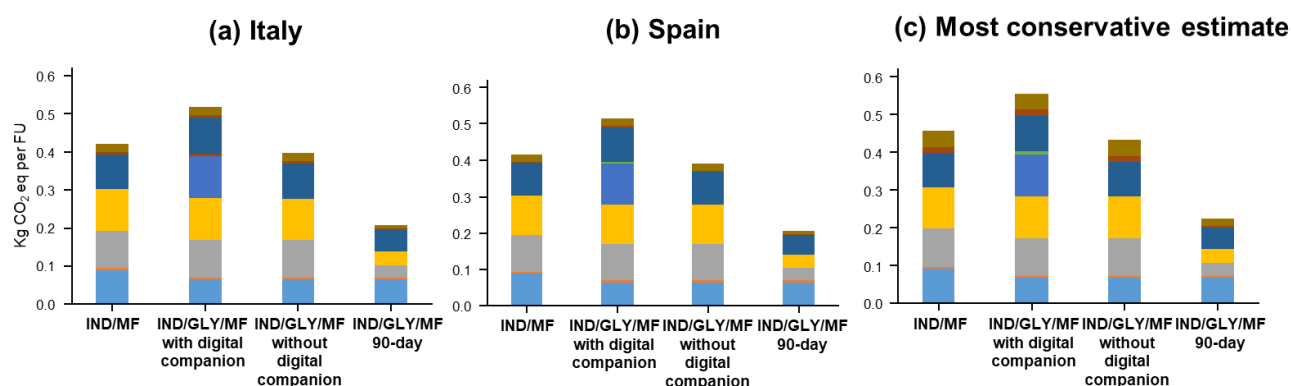
When looking at end-of-life routes, waste incineration without energy recovery has the highest CFP, as the carbon content of the device and packaging are released. While the most conservative estimate assumes 100% incineration without energy recovery, for Italy and Spain the findings were 10% and 12%, respectively. For Italy and Spain, 70% end-of-life routes were incineration with energy recovery.

Discussion

This study focusses on evaluating the CFP of Breezhaler® products in Italy and Spain, and more importantly providing a conservative estimate which can be used to understand the environmental impact of the Breezhaler® device in countries where such studies have not been conducted. It is an extension of a previously conducted analysis in four countries (France, Germany, Japan, and the UK) [2]. The analysis done in France, Germany, Japan, and the UK found that the largest contributions to the CFP came from active pharmaceutical ingredients, inhaler raw materials and packaging (plus, sensor raw materials wherever they were used). On the other hand, excipients, distribution, and end of life stages all made minimal contributions to the CFP for all the Breezhaler® products evaluated [3]. This data will allow comparisons with published evidence from other inhalation devices, to effectively make informed decisions on inhalation therapy.

Conclusion

The low CFP of the Breezhaler® device did not vary significantly among the considered countries (Italy and Spain), those evaluated previously and the conservative estimate. The Breezhaler® device has a consistent environmental impact in all geographies.



Life cycle stage	Geography	IND/MF (30-day) without digital companion	IND/GLY/MF (30-day) with digital companion	IND/GLY/MF (30-day) without digital companion	IND/GLY/MF (90-day) without digital companion
API	Italy	21%	12%	16%	30%
	Spain	21%	12%	16%	30%
	Most conservative estimate	19%	11%	15%	29%
Excipients	Italy	1%	1%	1%	3%
	Spain	1%	1%	1%	3%
	Most conservative estimate	1%	1%	1%	3%
Inhaler raw materials	Italy	24%	19%	25%	16%
	Spain	24%	19%	25%	16%
	Most conservative estimate	22%	18%	23%	15%
Inhaler production energy	Italy	26%	21%	28%	18%
	Spain	26%	21%	28%	18%
	Most conservative estimate	24%	20%	26%	17%
Digital companion raw materials	Italy	n.a	22%	n.a	n.a
	Spain	n.a	22%	n.a	n.a
	Most conservative estimate	n.a	20%	n.a	n.a
Digital companion production energy	Italy	n.a	1%	n.a	n.a
	Spain	n.a	1%	n.a	n.a
	Most conservative estimate	n.a	1%	n.a	n.a
Packaging	Italy	22%	18%	23%	27%
	Spain	22%	18%	23%	27%
	Most conservative estimate	20%	17%	22%	26%
Distribution	Italy	2%	1%	2%	2%
	Spain	1%	1%	1%	1%
	Most conservative estimate	3%	3%	3%	3%
Use	Italy	0%	0%	0%	0%
	Spain	0%	0%	0%	0%
	Most conservative estimate	0%	0%	0%	0%
End-of-life	Italy	5%	4%	5%	4%
	Spain	5%	4%	5%	4%
	Most conservative estimate	9%	8%	10%	8%

API, active pharmaceutical ingredient; GLY, glycopyrronium bromide; IND, indacaterol acetate; MF, mometasone furoate

Figure 1 - Figure and tabular legend depicting the percentage breakdown of the carbon footprint by life cycle stage for each product and geography in kg CO₂ eq per FU – (a) Italy, (b) Spain, (c) Most conservative estimate.

Table

Table 1. Carbon footprint comparison between Breezhaler® products (cradle-to-grave analysis)

Product	Geography	Total per life cycle (kg CO ₂ eq)	Total per day and dose (kg CO ₂ eq)	Total per month and FU (kg CO ₂ eq)	Total per year (kg CO ₂ eq)
IND/MF, 30-day	Italy	0.421	0.014	0.421	5.054
	Spain	0.416	0.014	0.416	4.996
	Most conservative estimate	0.449	0.015	0.449	5.383
IND/GLY/MF, 30-day with digital companion	Italy	0.519	0.017	0.519	6.232
	Spain	0.515	0.017	0.515	6.174
	Most conservative estimate	0.548	0.018	0.548	6.582
IND/GLY/MF, 30-day without digital companion	Italy	0.397	0.013	0.397	4.762
	Spain	0.392	0.013	0.392	4.705
	Most conservative estimate	0.424	0.014	0.424	5.092
IND/GLY/MF (90-day)	Italy	0.205	0.007	0.205	2.464
	Spain	0.203	0.007	0.203	2.441
	Most conservative estimate	0.218	0.007	0.218	2.615
FU, functional unit; GLY, glycopyrronium bromide; IND, indacaterol acetate; MF, mometasone furoate.					

References

[1] International Organization for Standardization: *Environmental Management—Life Cycle Assessment—Principles and Framework*, 2nd ed. Switzerland, 2006.

[2] Fulford B, Mezz K, Whiting A, Aumônier S: *Life Cycle Assessment of the Breezhaler® Breath-Actuated Dry Powder Inhaler*, Sustainability 2021; 13, 6657. <https://doi.org/10.3390/su13126657>

[3] Aumônier S, Whiting A, Norris S, Collins M, Coleman T, Fulford B, Breitmayer E: *Carbon footprint assessment of Breezhaler® dry powder inhaler*. (Abstract). Presented at: *Drug Delivery to the Lungs conference*, December 8-10, 2020; Drug Delivery to the Lungs. 31; <https://ddl-conference.com/ddl2020-christmas-lectures/conference-papers/carbon-footprint-assessment-of-breezhaler-dry-powder-inhaler/> (online only).