Summary for

Qiagen N.V.

on

Life Cycle Assessment of QIAGEN‘s QIAamp DNA Mini Kit (250)

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sustainable AG

Corneliusstraße 10
D-80469 München
Tel +49 89 20 20 56-42
Fax +49 89 20 20 56-50
info@sustainable.de
www.sustainable.de

sustainable

1. Background

QIAGEN conducted a Life Cycle Assessment (LCA) for one of its products, the QIAamp DNA Mini Kit. As one of QIAGEN's best-selling products, it is considered well suited to represent a large part of QIAGEN's products. QIAGEN splits its product portfolio into two categories: instruments and consumables & bioinformatics. The studied product is part of the largest category "consumables & bioinformatics", which about 90% of QIAGEN's sales (by turnover) are filed under. The studied product is therefore considered representative for this category. With about 2.5 kg, the kit is marginally heavier than an "average" QIAGEN kit.

Conformity with International Standards

This LCA is carried out in accordance to ISO 14040/14044, but is not certified by an independent third party.

Product description

The QIAamp DNA Mini Kit contains a series of collection tubes, bottled buffer solutions and so-called spin-columns used to isolate DNA from human tissue samples. DNA binds specifically to the QIAamp silica-gel membrane while contaminants pass through. Any inhibitors are removed in two wash steps, leaving pure DNA to be eluted in either water or a buffer provided with the kit. The kit yields DNA from samples ready to use in further procedures.

Scope of the study will be the full life cycle of the product, including extraction and processing of raw materials, transport to the customer, energy and material input required when using the product, as well as transport to the disposal facility and incineration of remaining materials. These system boundary settings are commonly referred to as "cradle to grave".

The product consists of 250 sampling elements and spin columns, accompanied by several buffer solutions and reagents in plastic bottles and packaged in a cardboard box.

Fillings

The manufacturing process of filling the bottles can be performed manually or automatically. For larger lot sizes, the automated process is chosen. For smaller lot sizes, for small filling volumes or in the case of particularities, the manual process is chosen. The filling of the bulk buffer is performed inside a cleanroom under laminar airflow.

Spin columns

The spin columns consist of a plastic collection tube and a spin column containing a membrane, a frit and a retainer ring. They are assembled by an automated spin assembly machine and afterwards blistered by an automated blister machine.

The plastic components, the material of the membranes and frits are purchased from a supplier. The frits are punched at QIAGEN by a separate punching machine and washed before further processing. The membranes are punched by the spin assembly machine during spin column assembly. The spin columns are blistered by an automated blister.

In the forming-station the forming-film is preheated and formed into pockets. At the feed area, the pockets are filled with spin columns by a robot. The sealing-foil is heat-sealed to the forming-film containing the product.

Packaging

All components are finally packed into a cardboard box accompanied by the necessary documents, sealed and are subsequently ready for shipping.

The product is sent off to customers around the globe via a global logistics provider. The products are sent off in large batches to a logistics hub, where the logistics provider takes responsibility for an efficient delivery. Secondary packaging is used if reasonable, with often two or more kits being packaged together.

Functional Unit

The functional unit of this LCA is defined as

Manufacturing, transporting to the customer and using one (1) QIAamp DNA Mini Kit with 250 spin columns and subsequent disposal by incineration.

System boundaries

All elementary flows at the incoming ecosphere boundary to the product system are considered. The product system includes the production of the spin columns, their packaging as well as packaging of the kit and its outer packaging for transport. The preparation of the buffer solutions and their packaging are also considered. After the kit is packaged and ready to be sent off to the customer, transport is considered with an average transport scenario, derived from QIAGEN's global geographical sales statistics (cp. Table 2). During the use phase of the kit, additional resources from the laboratory are required in order to be able to use the kit as intended, of which alcohol for preparing buffers, washing and diluting is considered in this LCA. To isolate the DNA, the spin columns are spun for a total of about 10 minutes in a micro-centrifuge. Electricity required for this step is also considered in the LCA.

The subsequent disposal of the kit's elements by incineration also lies within the system boundary. Elementary flows are almost entirely connected to predefined processes from the GaBi-Database, except for emissions from alcohol evaporation leaving the outgoing system boundary to the ecosphere.

Cut-Off Rules

Individual flows with less than 1% of the total mass of one kit (2,200 g) may be omitted, provided they do not aggregate to more than 3% of the total mass of one kit.

Energy resulting from energy recovery during incineration in the form of electricity and steam are being omitted, therefore no positive effects of possible energy recovery are considered.

Any by-product flows are also being omitted, notably from upstream paper and cardboard production. The burden for wastepaper recycling, which is being used in the cardboard packaging, is therefore attributed to this product system.

2. Data Basis for life cycle impact assessment

Most inventory data has been supplied by QIAGEN, partly with guidance by sustainable. The following table displays information on all relevant inputs (materials and energy) used for production, filling, transporting, using and disposing of the kit, including the buffer solutions and packaging.

All information in the following tables refers to the functional unit, i.e. the life cycle of one kit.

Electricity used in QIAGEN facility	12.9	kWh
Natural gas used in QIAGEN facility	2.2	kWh
Transport to QIAGEN facility	1,500	kgkm
Polypropylene, blow molded	1,310	g
Polyethylene, injection molded	149	g
Cardboard	500	g
Paper	4	g
PVC film	4	g
Deionized water	431	g
Ammonia (proxy for chemical compounds)	117	g
Transport by light truck	50	km
Transport by cargo plane	7076	km
Transport by truck-trailer	150	km

Transport by heavy truck	200	km
Transport by light duty vehicle	46,4	km
Isopropanol	50	ml
Electricity used at laboratory	3	kWh
Transport to incineration facility	500	kgkm

The following data for transportation were used for the impact assessment.

Share	Destination	Plane	Truck-trailer	Large rigid truck	Light rigid truck	Light duty vehicle
10%	Non-China Asia-Pacific	14,000	0	200	50	50
15%	Non-US Americas	12,000	0	200	50	50
10%	China	9,000	0	200	50	50
32%	US	7,800	0	200	50	50
3%	Africa	6,000	0	200	50	50
15%	Non-Germany Europe	2,000	500	200	50	50
15%	Germany	0	500	200	50	50
100%	Average	7,076	150	200	50	50

3. Life Cycle Impact Assessment Method

For the Life Cycle Impact Assessment, all elementary flows from (e.g. crude oil) and into the ecosphere (e.g. CO_2-emissions) are consolidated and factored into different impact categories, according to the chosen Life Cycle Impact Assessment method. The most prominent set of impact factors refers to Global warming and is published in the Intergovernmental Panel on Climate Change's (IPCC) assessment reports. It includes factors for atmospheric emissions to represent their impact on climate change, referred to as Global Warming Potential (GWP), and expressed as carbon dioxide equivalent (CO_2e).

The set of factors is part of the life cycle impact assessment method. The life cycle impact assessment method chosen for this LCA is published by the Institute of Environmental Sciences (CML - Centrum voor Milieuwetenschappen) of Leiden University in the Netherlands. Specifically, the LCIA method *CML 2001 (baseline), updated January 2016* was used. It contains impact categories such as, amongst others, acidification potential, global warming potential (excluding biogenic carbon), human toxicity potential and ozone layer depletion potential.

In this LCA, both weighting and normalization are used to derive the relative importance of impact categories. For this LCA, a set of region equivalents for EU25+3, (excluding biogenic carbon) was used as reference values. The weighting and normalization factors used in the chosen LCIA method have been updated in January 2016.

4. Results Overview

The results of the study are given in the table below, providing an overview for all impact categories. Moreover, it details the processes' shares of impact in the different categories. For most impact categories, the largest relative impacts result from the production of plastic, transport and electricity during production and use. Furthermore, cardboard and paper production play a role in some impact categories, as well as the incineration of plastics and the evaporation of alcohol during use.

Impact Category	Result	Unit	Processes	Share	Relevance*
Toxic effects on marine water systems (MAETP)	941	kg DCB eq.	Polypropylene	44%	47%
			Electricity	43%	
			Transport	9%	
			Polyethylene	1%	
			Rest	2%	
Depletion of fossil resources (ADP fossil)	289,0	MJ	Polypropylene	44%	19%
			Transport	31%	
			Electricity	13%	
			Polyethylene	4%	
			Rest	8%	
Global warming potential, excluding biogenic carbon (GWPe)	21,7	kg CO2 eq.	Transport	30%	13%
			Polypropylene	27%	
			PP incineration	19%	
			Electricity	16%	
			Rest	8%	
Photochemical creation of ozone ("summer smog") (POCP)	0,00638	kg Ethene eq.	Polypropylene	37%	9%
			Alc. evaporation	30%	
			Transport	23%	
			Electricity	9%	
			Rest	2%	
Acidification of soil and water bodies (AP)	0,0549	kg SO2 eq.	Polypropylene	43%	7%
			Transport	35%	
			Electricity	16%	
			Polyethylene	2%	
			Rest	4%	
Toxic effects on humans (HTP inf)	0,643	kg DCB eq.	Electricity	34%	3%
			Transport	23%	
			Polyethylene	20%	
			Polypropylene	7%	
			Rest	15%	
Depletion of abiotic resources, e.g. minerals (ADP elements)	1,7E-06	kg Sb eq.	Electricity	57%	<1%
			Rest	43%	
Eutrophication (over-enrichment of nutrients in water bodies) (EP)	0,00744	kg Phosphate eq.	Transport	54%	<1%
			Rest	46%	
Toxicity to freshwater ecosystems (FAETP)	0,0731	kg DCB eq.	Transport	41%	<1%
			Rest	59%	
Depletion of ozone (i.e. the ozone layer) (ODP)	8,4E-11	kg R11 eq.	Paper	94%	<1%
			Rest	6%	
Toxic effects on terrestric systems, i.e. soil (TETP)	0,00563	kg DCB eq.	Electricity	52%	<1%
			Rest	48%	

Table: Overview of impact results.

*Relevance is calculated as the share of weighted and normalized impact of the respective category.

To contextualize the resulting values for all impact categories, they are interpreted against the goal and scope of the study. The share of weighted and normalized impacts in each category – paraphrased here as "relevance" – is used as a guidance in this section. Categories with a high "relevance" rating contribute more to this product system's impact profile than others. Note that the "relevance" rating is based on weighting and **should therefore be considered subjective**. The "relevance" rating on its own is therefore not suited for strategic decision-making and should be understood as a rough indication of the impact profile specific for this product system.

Generally, most processes and materials are driven to be the largest contributors to most impact categories by their energy demand. Impacts from transport, electricity generation and plastics production therefore lead most categories. About half of electricity is consumed for production, the remainder is used in the labs to spin the columns. Note that the electricity demand is modeled to be met by the European electricity mix.

The relevance rating described above makes **ecotoxicity** impacts to marine aquatic systems a very relevant issue. Production of polypropylene causes the highest impact in this category, closely followed by electricity generation. Note that impacts from polypropylene production are independent of the varying aspects like customer location. Impacts from electricity generation in turn will vary with the lab's efficiency and the local electricity mix. The same is true for transport, which ranks third in impact for this category, but depends heavily on the transport distance to individual customers.

Depletion of fossil resources is second rated in relevance. Plastics have multifold impacts in this category, due to them being made from fossil resources and depleting a large amount of fossil resources for meeting the energy demand during their production. Transport and electricity generation both use large amounts of fossil resources for fuel and therefore rank second and third in impacts to this category.

Global Warming Potential is rated third in relevance. This showcases the subjective nature of the weighting process, as the method used in weighting does not account for urgency. Climate change is arguably the most urgent global environmental challenge. Again, impacts in this category are closely linked to energy demand. Transport contributes the largest impact in this category, followed by plastics and electricity production. Plastics also have multifold impacts here, since their embodied carbon is released to the atmosphere during incineration. Note that a possible energy recovery is not considered in this LCA, which would reduce the impact in this and other categories. Different assumptions regarding disposal could significantly change the overall impacts of the product system, ranging from recycling (likely to have beneficial impact) to landfilling (likely to have adverse impact). Although open dumps and landfills are the most prevalent form of solid waste disposal globally, incineration at the end of life is deemed an accepted and reasonably conservative approach for this product.

Photochemical creation of ozone, often referred to as summer smog, rates fourth in relevance. Although plastics, transport and electricity generation are large contributors to this category, the use phase plays a special role: Specifically, evaporation of alcohol used for washing and diluting samples during the use of the kit contributes significantly to this category. Volatile organic compounds tend to react with nitrogen oxides under sunlight in the lower atmosphere, causing ozone to be present near ground-level. This is not to say that the evaporation of the considered amount of alcohol is a large contributor to summer smog creation (evaporation from e.g. vehicle tanks will exceed that by far). It should rather be read as an indication of the impact profile of the studied product system.

Acidification of soil and water bodies is ranked fifth in relevance. Plastics production contribute most to this category, followed by transport end electricity generation.

Finally, toxic effects on humans are rated sixth in relevance. Impacts in this category stem from electricity generation as well as transport and plastics production. Except for ozone depletion, all remaining impact categories are dominated by impacts from transport or electricity generation. Regarding ozone depletion, paper and cardboard production contribute more than 90% of this category's impact.

5. Assumptions and limitations

Electricity generation causes a large amount of the impact in this LCA. The generation was modeled using an average European electricity mix. Since Europe has a relatively "clean", i.e. greenhouse gas efficient, electricity mix, the impact could turn out higher than the results suggest. Using the kit in geographic regions with a high emission factor, like the US or China, could easily double or triple the emissions in the use phase

To ensure comparability of the LCA, electricity generation follows a location-based approach. This means the electricity mix is modeled according to a production mix in a certain geographic region, rather than for a specific electricity supplier. The emission intensity of individual contracts, e.g. for renewable electricity supply, is therefore not considered. When alternatively following a so-called market-based approach, individual contracts' electricity mixes can lead to very different results in many categories, including much lower Global Warming Potential. By modeling electricity production according to contracts with 100% certified production from renewable electricity, most impact categories would show significantly lower results, with exceptions in some categories, that do not benefit from renewable electricity generation.

Biotechnology is a challenging sector for LCA studies, especially when some of the chemicals reach the ecosphere untreated. This LCA assumes proper disposal of all elements and residuals of the kit. Improper disposal, for example in run-off water, could have massive negative effects on many impact categories.

In addition, the disposal of the kit's elements via combustion yields electricity and heat. These flows are omitted in the model, assuming that these energy flows are lost to the atmosphere, i.e. no form of energy recovery takes place. By assuming an avoided burden for electricity production from fossil fuels, one could incorporate a credit for these energy flows, reducing the impacts of several impact categories, including Global Warming Potential.

Supplier-specific data has not been used in all occasions, for example to model the plastic containers. An average European consumption mix was used, which is advisable unless more precise information, for example on the specific production method and share of recycled material, is known. Using bottles from 100% recycled plastic could significantly reduce impacts in several categories.

Transport is another very impactful activity during the products life cycle. Concerning data quality, the transport model was fed with statistical information from QIAGEN, therefore the share of transport in the overall impacts is considered representative. Still, the datasets available in the databases are modeled to represent regular logistics. They are therefore less specific for package, parcel, or express delivery services and the like, which increasingly resemble the distribution activities of QIAGEN's kits, the closer the transport approaches the last mile to the customer. Especially for time-critical deliveries, emissions and therefore impacts could turn out much higher, due to smaller vehicles being used for less efficient transport, transporting fewer kits at a time.

6. Product life[1]

Longevity: Stored under proper conditions (room temperature), the product has a shelf life of one year. It is offered in different sizes, such that high-throughput customers can order larger kits, while a small customer should be able to consume the product before its shelf life is reached.

[1] Note that the content of this section only refers to the studied product, not the full QIAGEN product portfolio.

Repairability: The product is a consumable, consisting of many individual consumable elements. Repairability is therefore not considered a relevant characteristic. The number of elements in the kit is designed to be exactly the right amount necessary for the intended use. The exact composition of some kits is stipulated by regulatory bodies. For non-regulated kits, such as the QIAamp DNA Mini Kit, individual elements can be ordered separately if needed.

Reusability: The product is a consumable. Reusability is not considered a desirable characteristic to effectively avoid biological cross-contamination and ensure consistent DNA yield.

Recyclability: Individual elements of the kit are produced from single varieties of material (cardboard, polyethylene, polypropylene). After use however, some elements of the kit are to be considered hazardous waste and therefore should not be recycled, depending on local regulation.

Upgradability: The compatibility of individual elements of the product with other products is described in the supplied instructions for use. Apart from that, upgradability is not considered a sensible characteristic of this consumable product.

7. Material efficiency (consumables)[2]

Company position: The chemical compound used for sample preparation, guanidine hydrochloride, is one of the most potent protein denaturants available today, which in return means that a minimal amount is enough for 250 DNA samples. The studied product only contains about 100 g of guanidine hydrochloride. The plastic bottles holding the chemicals and buffer solutions, which are an essential part of almost every QIAGEN consumable, have been subject to design changes in the past, with a focus on safety, usability as well as material efficiency. Buffer solutions are provided as concentrates whenever possible, such that the total weight of material being transported is reduced to a minimum. Prior to use, the consumer simply adds ethanol to the concentrates.

Targets: QIAGEN aims to reduce the amount of packaging material for the chemicals and buffer solutions, as well as their secondary packaging for shipping, to a minimum. Due to the worldwide shipping and use of the sensitive products, a certain amount of secondary packaging is considered unavoidable.

[2] Note that the content of this section only refers to the studied product, not the full QIAGEN product portfolio.

Measures and reporting on progress: QIAGEN is continuously improving on product design. Starting this year, quantitative methods such as life cycle impact assessment accompany this process.