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Date: 6th of April 2020

Kaneka Biodegradable Polymer PHBH™ are "natural polymers that have not been chemically modified"

In May 2019, the EU adopted Directive (EU) 2019/904 on the reduction of the impact of certain plastic products on the environment ("SUP Directive"). Member States must transpose the SUP Directive by 3rd of July 2021.

In this Directive, a plastic is defined as a material consisting of a polymer to which additives or other substances may have been added, and which can function as a main structural component of final products, with the exception of natural polymers that have not been chemically modified (Article 3(1) Definition – Plastic). This means that 'natural polymers that have not been chemically modified', in the sense of the REACH definition of a not chemically modified substance (Article 3(40) Reach and Recital 11 of SUP Definition – Not chemically modified substance) should be exempted from the SUP Directive.

Below we set out (1) how Kaneka PHBH™ must be considered to be 'natural polymers that have not been chemically modified' as the term used in the SUP Directive, and (2) how the use of Kaneka PHBH™ in single-use products is consistent with the intent and advances the goals of the SUP Directive. These positions are evident not only by the plain meaning of the terms, but also in the context of the purpose of the SUP Directive, EU Plastic Strategy and similar environmental legislations.

[redacted]

1) Kaneka PHBH™ is a natural polymer that has not been chemically modified

Polyhydroxyalkanoates (PHAs), including poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate) (PHBH), occur in nature and are part of the metabolism of the micro-organisms. PHBH is biosynthesized within living micro-organisms via a set of complex biochemical reactions within the bacterial cell. When so produced, and as part of the micro-organism's own metabolism, it may serve as both a source of energy and as a carbon store. PHBH is produced in micro-organisms such as *Aeromonas caviae* and *Aeromonas hydrofilla*[1]. Due to its natural origin, PHBH are well-known to undergo biodegradation in natural environments.

Kaneka PHBH™ is biosynthesized through fermentation technology. Kaneka's proprietary fermentation process uses renewable biomasses (such as plant oils) as raw materials. These biomasses are converted into PHBH via a set of complex reactions in the bacterial cell.

Independent research has cleared that the PHBH synthesis pathway within Kaneka's fermentation process is identical to the PHBH synthesis pathway within wild micro-organisms. (see Annex 1). Kaneka PHBH™ "polymerization" process within Kaneka's strain in fermentation, is exactly the same as the PHBH "polymerization" process in wild strain occurring in nature**.** By this, we can conclude **Kaneka's PHBH™ is based on a polymerization process that happens in nature**.

Through the fermentation process, the chemical structure remains unchanged compared to PHBH within wild micro-organism, which is verified by the fact that **Kaneka PHBH™ polymers are exactly the same in chemical identity, composition and structure as other PHBH polymers present in the natural environment**. (see Annex 2)

There is no question that PHBH polymers are biosynthesized and occur naturally in the environment. Kaneka PHBH™ "polymerization" process within Kaneka's strain in fermentation, is exactly the same as the PHBH "polymerization" process in wild strain occurring in nature. Spectrographic analyses conducted by third party laboratory shows that Kaneka PHBH™ polymers are exactly the same in chemical identity, composition and structure as other PHBH polymers present in the natural environment. Thus, we can conclude that **Kaneka PHBH™ is unmodified natural polymer.**

Paragraph 11 of the recital of the SUPD makes clear that in order for polymer substances to qualify as "*natural polymers*" for the purpose of Article 3(1) of the SUPD they must "*occur naturally in the environment*". Also, according to paragraph 11 of the recital, polymer substances which are chemically modified do not qualify as "*unmodified natural polymers*" as they do not "*occur naturally in the environment*".

[1] As cited in United States Patent 5,292,860 dated March 8th , 1994, Shiotani et al.

2) Excluding PHBH from use in SUP is counter to the objectives of the Directive

The objectives of the SUPD are therefore threefold:
(1) to prevent and reduce the impact of certain plastic products on the environment;
(2) to promote the transition to a circular economy with innovative and sustainable products and materials; and
(3) to contribute to the efficient functioning of the EU Single Market.

The scope and meaning of Article 3(1) of the SUPD should be interpreted in light of these underlying objectives.

As regards the first objective: there is no question that the use of PHBH polymers clearly prevents and reduces the impact of plastics and plastic products that are persistent and harmful in the environment.
As regards the second objective: there is no question that PHBH polymers are "innovative and sustainable products and materials" – which offer a safe and sustainable alternative to plastics which are persistent and harmful in the marine and other environments. Excluding or ruling out the use of PHBH polymers would undermine and prevent the transition to a circular economy, and would, in fact, serve to actually create more products legally classified as "waste" and thereby undermine the very objective of the circular economy and the SUPD.
As regards the third objective: The Commission must act as the Guardian of the Treaties and to the best interests for the promotion and growth of the EU single market. This includes highlighting and promoting "innovative and sustainable products" – like PHBH polymers – as viable and safe alternatives to plastics which are persistent and harmful to the marine and other environments – therefore it should be stated explicitly and without ambiguity in the Commission Guidance that PHBH polymers are "natural polymers that have not been chemically modified".

In addition to being 'natural polymers', the PHBH polymers are marine biodegradable which has been certified by TUV Austria and sustainable materials. KANEKA PHBH^{TM} biodegrades within a time scale short enough for them not to be harmful to marine life and not to lead to an accumulation of plastics in the environment. It does not disintegrate into microplastics but biodegrads into CO2 and water. Other EU legislation specifically acknowledges the benefits of these types of materials and aims to address these materials in an appropriate way such as

promoting their use in order to transition to a Circular Economy[2]. Plastic Strategy says that *the Commission is particularly attentive to innovation on materials that fully biodegrade in seawater and are harmless for the environment and ecosystem*. The Strategy also recognizes that *targeted applications, such as using compostable plastic bags to collect organic waste separately, have shown positive results. Composting fits into circular economy through organic recycling.* Also, the European commission updated Bioeconomy strategy[3] is expressing the potential of the bioeconomy to contribute to tackling plastic pollution, for example, to mobilize the key actors in the plastics value chain to support the development of substitutes to fossil resources, in particular biobased, recyclable and marine biodegradable substitutes for plastic.

It appears contrary to the intent of the SUP Directive that biodegradable polymers would be subject to the restrictions, as is stated in paragraph 11 of the recital. However, it is important to note that the SUP directive defines 'biodegradable plastic', in part, as plastics that are "*recoverable through composting and anaerobic digestion*". Indeed, it may be possible for a plastic that has demonstrated compostability or anaerobic degradation to resist biodegradation in a marine environment. Such is not the case for PHBH, which has been certified by a third party laboratory to be biodegraded in the marine environment within reasonable time period.

The fundamental objective of the SUP Directive, EU Plastic Strategy and the circular economy which SUP Directive and Plastic Strategy aim to assist in creating, can only be achieved if the types of materials such as the Kaneka PHBH™ polymers, are permitted and recognized as natural polymers.

[2] As an example, the proposed REACH Restriction on microplastics includes a derogation for "*polymers that are (bio)degradable*". The criteria for 'biodegradable' are defined in great detail in Appendix X to the REACH Restriction, including a number of OECD and EN ISO test methods. https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18244cd73

[3] "A sustainable Bioeconomy for Europe: strengthening the connection between economy, society and the environment", Directorate-General for Research and Innovation, 2018

Annex 1: PHBH synthesis pathway

The PHBH synthesis pathway within a wild strain (Aeromonas Caviae FA440) has been described by Fukui and Doi in 1997[4] whereby (*R*)-3-hydroxybutyryl-CoA ((*R*)-3HB-CoA) and (*R*)-3-hydroxyhexanoyl-CoA (*R*)-3HHx-CoA) are co-polymerized by PHA synthase (PhaC) to generate PHBH inside of the cell of the microorganism *Aeromonas caviae* FA440. (see figure 1)

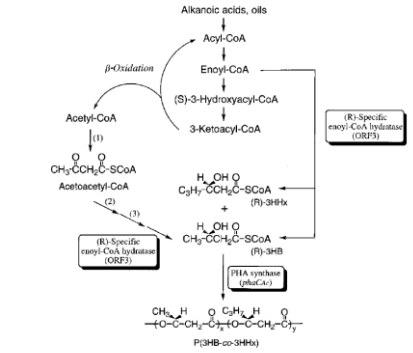


FIG. 4. Proposed pathway of P(3HB-co-3HHx)-biosynthesis in *A. caviae* from alkanoic acids or oils. (1) β-Ketothiolase; (2) NADH-acetoacetyl-CoA dehydrogenase; (3) crotonase [(*S*)-specific enoyl-CoA hydratase].

Figure 1: PHBH synthesis pathway in wild strain

Kaneka's PHBH™ synthesis pathway has been described by Arikawa and Matsumoto in 2016[5]; whereby the same pathway as within the wild strain has been confirmed: (*R*)-3-hydroxybutyryl-CoA ((*R*)-3HB-CoA) and (*R*)-3-hydroxyhexanoyl-CoA (*R*)-3HHx-CoA) are co-polymerized by PHA synthase (PhaC) to generate Kaneka's PHBH™ inside the cell of Kaneka's strain.(Figure 2)

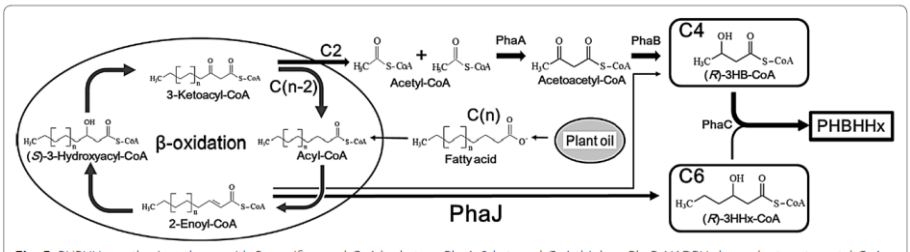


Fig. 5 PHBHHx synthesis pathway with *R*-specific enoyl-CoA hydratase. PhaA, 3-ketoacyl-CoA thiolase; PhaB, NADPH-dependent acetoacetyl-CoA reductase; PhaC, PHA synthase; PhaJ, *R*-specific enoyl-CoA hydratase; (*R*)-3HB-CoA, (*R*)-3-hydroxybutyryl-CoA; (*R*)-3HHx-CoA, (*R*)-3-hydroxyhexanoyl-CoA

Figure 2: Kaneka PHBH™ synthesis pathway

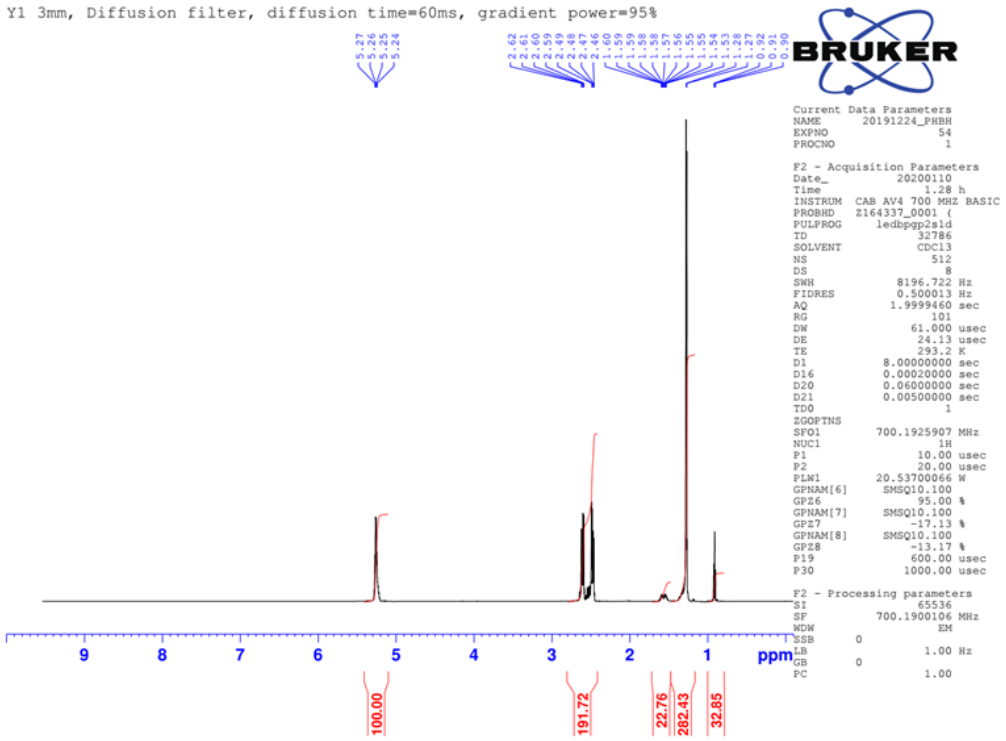
[4] Fukui and Doi. *Journal of Bacteriology* (1997) 4821-4830
[5] Arikawa and Matsumoto. *Microb Cell Fact* (2016) 15:184

Annex 2: Spectrographic analysis of Kaneka PHBH™ compared to PHBH

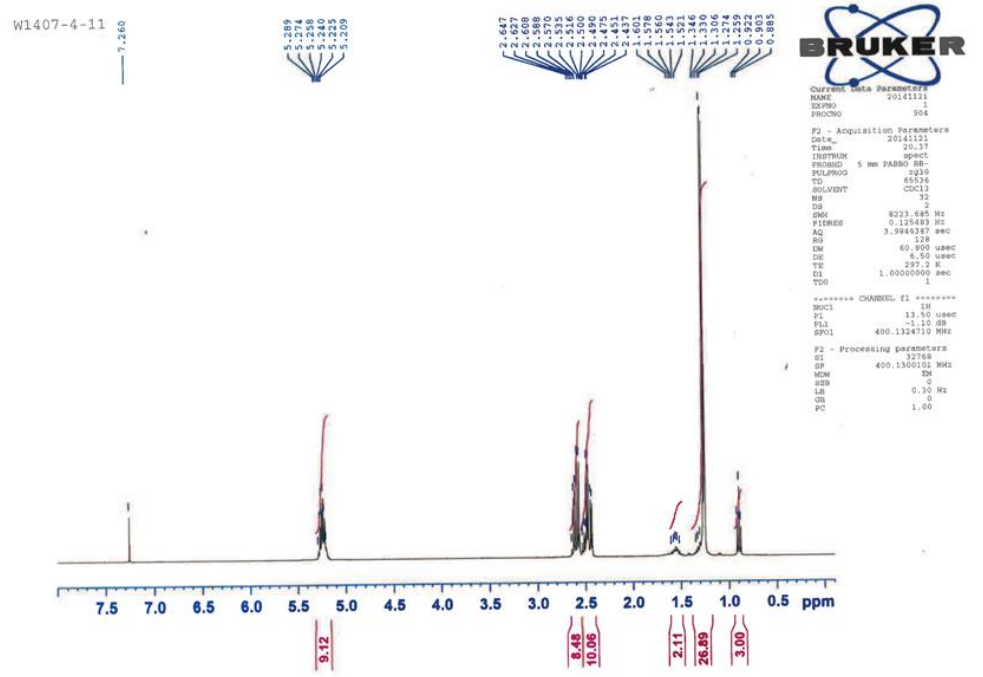
Wild strain (*Aeromonas caviae* FA440) has been cultivated to collect enough quantity of PHBH for spectrographic analysis. This material has been compared with Kaneka PHBH™ by means of NMR and GC/MS by a third party laboratory. As a result, convincing data has been obtained which proves that chemical structure of KANEKA PHBH™ is the same as that of PHBH occurring in nature.

1) [1]H-NMR analyses

Material accumulated in the body of the wild strain, *Aeromonas caviae* FA440

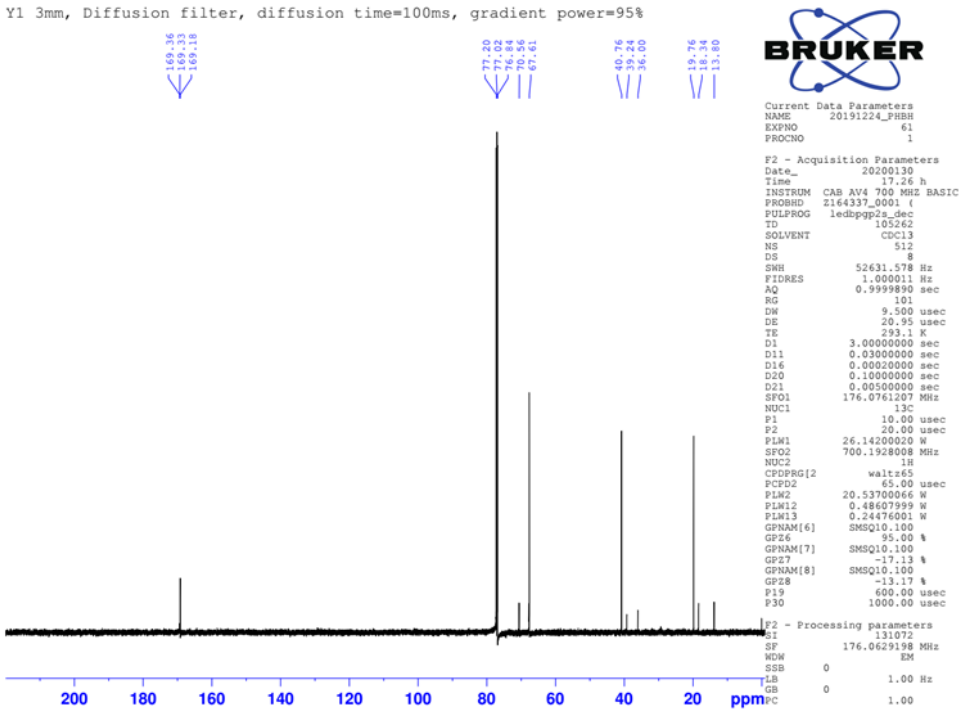


Kaneka Biodegradable Polymer PHBH™

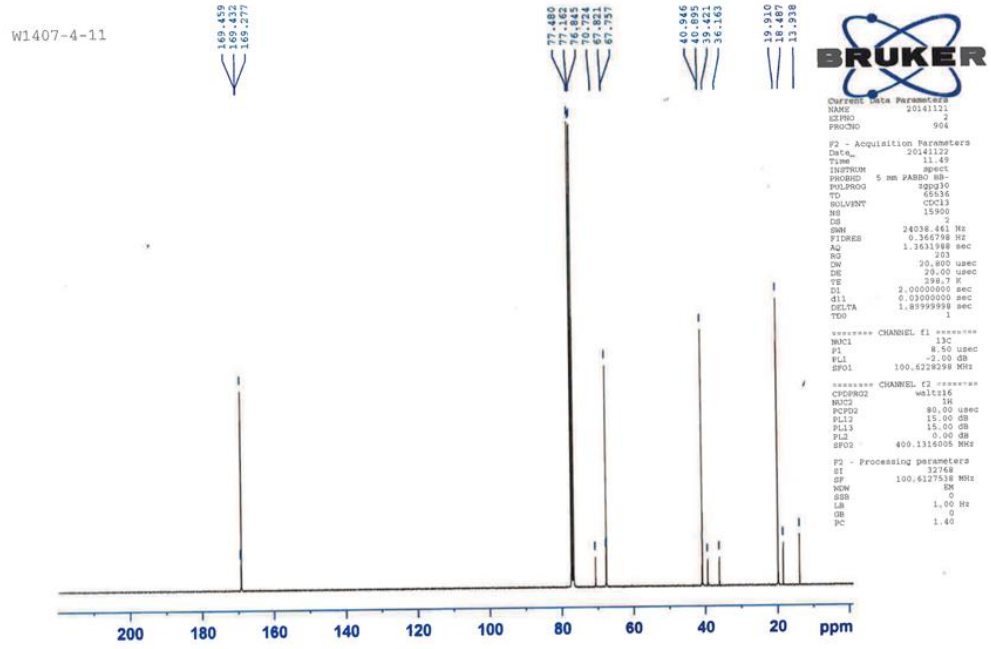


2) ^{13}C-NMR analyses

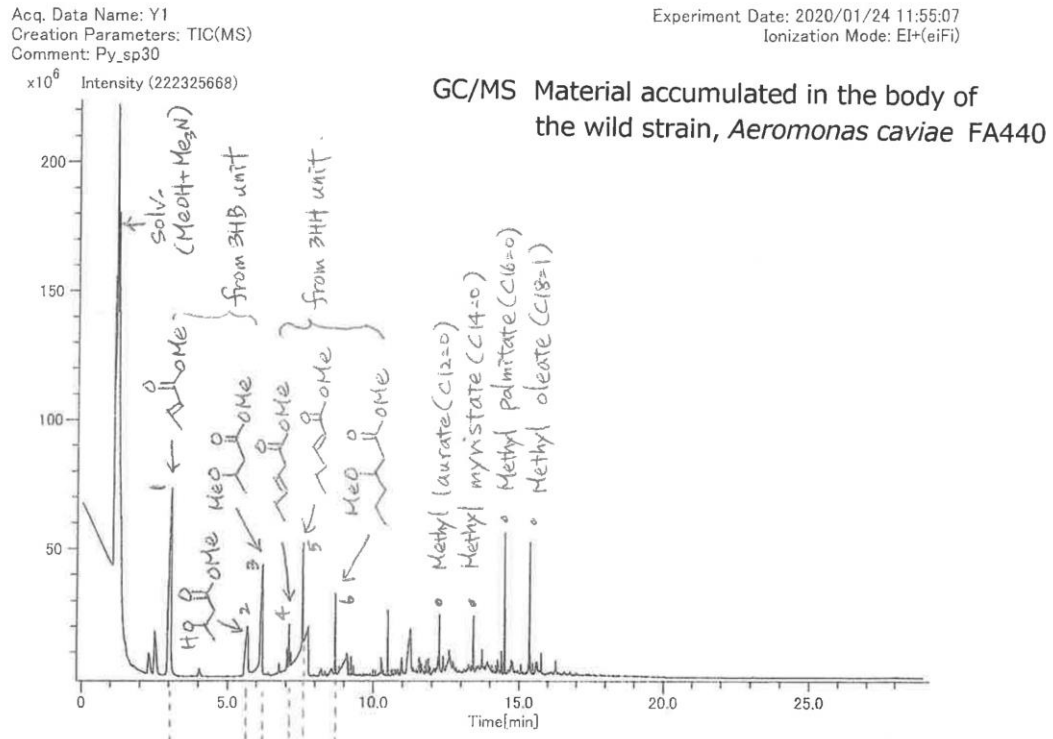
Material accumulated in the body of the wild strain, *Aeromonas caviae* FA440

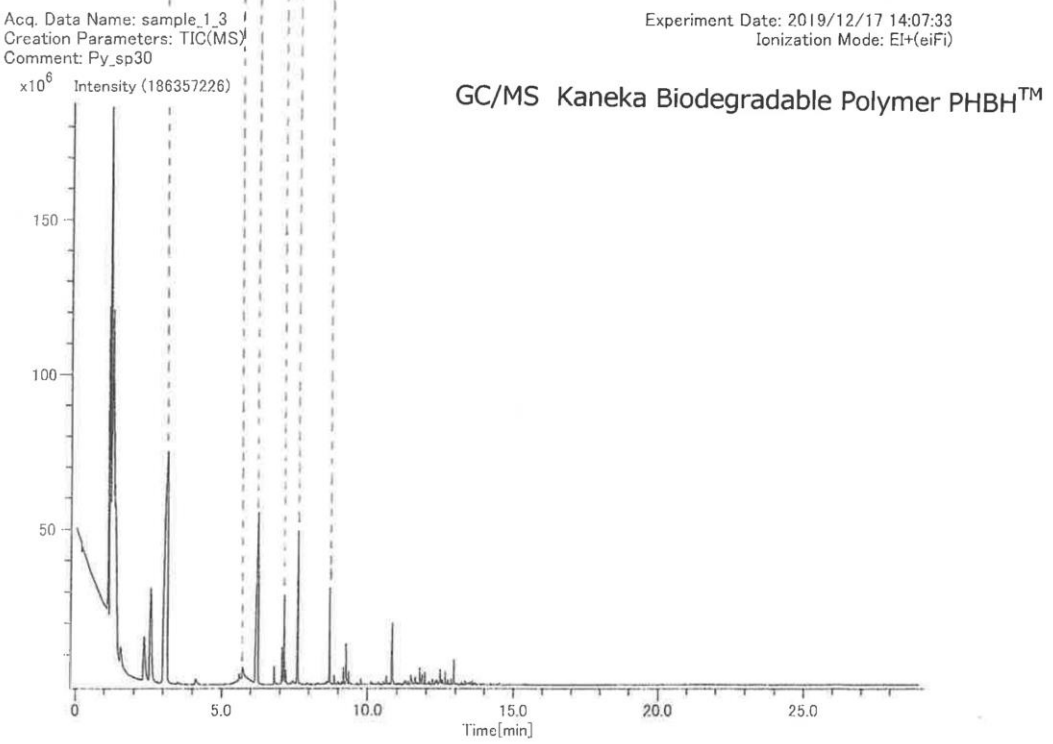


Kaneka Biodegradable Polymer PHBH™



3) Reactive Pyrolysis GC/MS analyses





Annex 3 : Kaneka

Kaneka Corporation, established in 1949 and headquartered in Osaka and Tokyo, produces chemical intermediates such as chemicals, functional plastics, expandable plastics & products, foodstuffs products, life-science products, electronic products and synthetic fibers. Kaneka worldwide employs more than 10,000 people.

Besides production sites in US, Singapore, Malaysia, China, Vietnam, India, Taiwan, South Korea and Australia, Kaneka's main production site in EU is in Belgium (Kaneka Belgium NV).

Kaneka Belgium NV was founded in 1970. Currently, it operates three production units in Westerlo-Oevel. Kaneka Belgium NV has become a solid cornerstone of the Kaneka global network.

As a good corporate citizen, Kaneka is committed to address the environmental challenges of our planet, to contribute to the circular economy and to a better quality of life of our societies.

Kaneka participated to the "**EU Recycling Pledge**"[6] and has pledged to provide the European market with 60,000 tons through 2025 of innovative biodegradable polymer named PHBH™, which has been certified as home-compostable, soil biodegradable, and marine biodegradable by an independent certification body (TÜV Austria Belgium), including for food packaging applications which:

- are difficult to recycle in a mechanical way due to high contamination level;
- can be fully recovered into organic fertilizer products via organic recycling; and
- biodegrades in marine environment in case of accidental losses.

[6] https://circulareconomy.europa.eu/platform/en/commitments/pledges/kaneka-belgium-nv