

NATUREWORKS ON PRODUCT SAFETY & TOXICITY

ADDRESSING PRODUCT SAFETY

All plastics are made by joining together simple building blocks into long chains. Today, we use plants to capture and sequester CO₂ transforming it into long-chain sugar molecules. We ferment those sugars to make lactic acid, a natural product that's present in yogurt and that build up in our muscles after some hard exercise. This lactic acid is the building block for the all the Ingeo (PLA) biomaterials we produce.

One of the key attributes of Ingeo is that the lactic acid building block exists in "left hand" and "right hand" versions (molecules that are mirror images of each other). By varying how we blend these, we can alter the physical properties of the grades we sell enormously, while still using only lactic acid. This is a fundamentally different approach than some existing plastics that must use other additives such as plasticizers to adjust their properties for different end uses.

We're able to produce Ingeo that on the one hand makes a t-shirt (replacing polyester), on the other hand a rigid yogurt cup (replacing polystyrene), on the other hand, a baby wipe (polypropylene), on the other hand, a flexible film (chip bags, etc), and on the other hand, durable goods, substituting polycarbonate. We do all this without adding BPA, phthalates, PFAS, or many other chemicals of concern.

While the concerns around plastics, toxicology, and human health are very real, we employ multiple methods for testing and certifying that Ingeo biomaterials are safe. Where we partner with the supply chain to develop finished goods, our stewardship extends ensuring additional testing for safety on these products.

We don't ask our customers to take only our word for safety – we have it vetted by independent, 3rd parties like the [Cradle to Cradle Products Institute](#) (C2C, co-founded by Michael Braungart also the founder of [EPEA](#)) where we were awarded a [Gold level Material Health Certificate in 2018](#).

When used as a food packaging material, Ingeo is fully compliant with long-standing global legislation for [food contact requirements](#) including both in the US and EU. However, we not only meet governmental requirements, but we go one step beyond that by having a non-governmental organization like C2C 'kick the tires' and provide their own opinion and certification.

While we work hard to make a fundamentally safe material, we realize that once it leaves our hands of course, the material is out of our direct control, and so we use a variety of techniques and approaches here:

- i) We have a 'chain of custody' mentality (we want to know our customers, and we want to know our customer's customers). We're not simply selling a box of Ingeo plastic pellets with a 'hands off approach'.

We've introduced a brand new-to-the world material, and we're working hand in hand with our customers to get this to the market.

- ii) We also take a contractual approach providing customers and Ingeo-brand licenses with a [prohibited substances policy](#) they are required to adhere to – a requirement not often found when buying commodity grade petrochemical-based plastics.

- iii) We randomly sample Ingeo-brand licensees and check what they are making with our biomaterials.
- iv) We use a 3rd party approach having organizations like the Cradle to Cradle Products Institute certify the safe composition of Ingeo. ([View our certificate here](#))

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BACKGROUND SUMMARY

A 2019 study entitled “*Benchmarking the in Vitro Toxicity and Chemical Composition of Plastic Consumer Products*” published in the Journal of Environmental Science & Technology, sets out to benchmark the toxicological and chemical signatures of a selection of plastic consumer products, manufactured from eight polymer types: PVC, PUR, PET, HDPE, LDPE, PS, PP, and PLA¹. The lead author draws many conclusions, among them the claim that “High baseline toxicity was detected in all “bioplastics” made of polylactic acid (PLA)”, and that little to no toxicity was found in HDPE and PET. The study was based on samples of each plastic type, purchased at retail, and for PLA included 4 samples identified as a yogurt cup, a vegetable tray, a shampoo bottle, and coffee cup lid.

However, despite those claims in the paper title and abstract, the conclusion of the study is quite clear that no links to human health can be drawn from their preliminary data; the chemicals they note are only tentatively identified; and that their methodologies are outside the globally well-established testing protocols used in the US and EU for plastic articles in food contact applications.

While we agree with the last line of this paper “Acknowledging their chemical complexity is the first step towards developing new scientific and regulatory approaches to improve their safety,” we suggest that this same complexity led them to some erroneous conclusions.

In our assessment, the preliminary results reported in this paper are inconsistent and result in misleading conclusions that do not support the claims made in the paper’s title or abstract.

KEY OBSERVATIONS ON THE STUDY

- The paper itself states ***“it is important to highlight that our aim was not to draw conclusions regarding the health impacts of plastics.”***
- None of the chemicals tentatively identified in the PLA articles studied in this report are found in the Ingeo PLA grades we sell. However, more fundamentally, we are concerned that three of the four products identified as PLA are likely misidentified and that some or all of the chemicals that the authors list have also likely been misidentified.
 - On identifying the products, the provided FTIR spectra used to identify PLA samples listed as 1 and 3 are not consistent with PLA. The FTIR spectrum for sample 4 appears to be insufficient for identifying any components including PLA. Previously published spectra for PLA are available in scientific literature².

¹ polyvinyl chloride (PVC), polyurethane (PUR), polyethylene terephthalate (PET), high-density polyethylene (HDPE), low-density polyethylene (LDPE), polystyrene (PS), polypropylene (PP), and polylactide (PLA).

² [Preparation and Characterization of Poly\(Lactic Acid\)-g-Maleic Anhydride + Starch Blends](#) and [Preparation and characterization of interpenetrating networks based on polyacrylates and poly\(lactic acid\)](#)

- On the chemicals, the paper itself states, “We refer to the latter chemicals as **tentatively identified** as **we did not use authentic standards to confirm their identity**”.

This could have been quickly addressed if the had authors purchased commercially available reagent grade standards of most, if not all, of the “high priority chemicals” listed in Table 2 and conducted spiking experiments to confirm or refute their presence in the extracted samples.

“The chemical screening with GCQTOF-MS is certainly limited because it is selective to semi-volatile and nonpolar organic compounds. Accordingly, nonvolatile and polar compounds will be underrepresented in our data.”

The authors further caveat that the databases they used are limited: “We decided to use GC-QTOF-MS because comprehensive spectral libraries for compound identification are available. However, the NIST (National Institute of Standards and Technology) database may be limited in their coverage of plastic-associated chemicals, especially NIAS (non-intentionally added substances), and **the rate of false identifications might be high.**”

- Also, specific examples of misread properties used for identification of chemical substances are found in the study's provided data. For example, samples referenced as PLA 1 and PLA 2 both state that a species defined as methyl propionate is found with a retention time of 8 mins, this indicates good reproducibility between GC-MS analyses. However, in sample PLA 3, they indicate the presence of a species they define as benzyl alcohol with a retention time of 6.6 mins. The column and conditions used for chromatography separate compounds based on boiling point. In an instrument that separates and distinguishes species by their boiling point (lowest boiling point appearing first), one cannot reconcile the result that a compound with a boiling point of 205°C (benzyl alcohol) has a retention time much shorter than a compound with a boiling point of 78°C (methyl propionate).
- We are also concerned about the process used to determine if the tentatively identified chemicals induce *in vitro* toxicity. The study used a fast, low-cost bioassay that only measured bioluminescence (the production and emission of light by a living organisms such as bacteria) without determining the actual cause of what influenced bioluminescence, using it as an indeterminate proxy for actual toxicity. Where bioluminescence was diminished, there was no follow-up cell viability assessment. In this test, common food ingredients such as salt, glycerol, and vinegar will also prove to be toxic.
 - From the paper: “We used ToxCast data to prioritize the detected compounds according to their *in vitro* toxicity and retrieved high throughput data for 23% of the chemicals. **This highlights that toxicological data is unavailable for most of the known chemicals.**”
 - “The same may be true for the ToxCast (EPA's Toxicity Forecaster) data, which in addition **might be prone to false-positives and -negatives.**”
- The authors tested commercial products obtained from stores such as supermarkets. They did not use a rigorous method for cleaning these materials, simply rinsing them with ultrapure water “until residues were completely removed”. This cleaning protocol does not have the rigor required when preparing samples for trace analysis by GC/MS.

Because of this, it's quite possible that some of the detected chemicals originate from the product found in the plastic packaging, or from contamination of packaging during consumer handling in the stores.

- For example, in the PLA shampoo bottle tested, the tentatively identified fatty acids occur in nature and are commonly used as surfactants (for lather and foaming) in soaps and shampoo. They are not chemicals used in PLA production or processing.
- We question the methodology of using methanol in this testing. It is not a common solvent for extracting additives from all plastic products, nor is it used when performing food contact studies under well-established testing protocols as legislated in the US and EU.

- For example, methanol, a very polar solvent, is not commonly used for extracting additives from plastic products of widely varying polarity.

HDPE and PET are nonpolar plastics, so choosing a polar solvent like methanol means the testing did not provide a "level playing field" for assessing extractables where the nonpolar plastics did not properly swell to allow the extraction of additives. This creates potential for a misleading conclusion that these materials are free of any additional substances or chemicals.

It's not surprising that "toxicities" evaluated in this study were higher for the polar plastics (e.g. PVC, PUR, PLA) versus the more nonpolar plastics (e.g., HDPE, PET). Perhaps more meaningful results could have been obtained using methanol and nonpolar solvent like hexane or toluene as extraction solvents.

- The author's comment on the choice of methanol: "*We selected methanol because it was the only solvent that did not dissolve any of the polymers*". However, common mixtures used to look for migration of compounds from food packaging to food stuffs such as 10% ethanol / 90% water and 3% acetic acid / 97% water would not have dissolved any of the polymers tested and would have provided a more useful dataset.
- We question the identification of the following chemicals that the authors associated with PLA articles. We also question why some of these substances should be considered "high priority chemicals" because they are commonly found both in food and in our bodies:
 - Oleic acid – major fatty acid component of lipids found in cell membranes and in olive oils
 - Dodecanoic acid – major fatty acid found in coconut oil
 - Methyl propionate – used as an ingredient in fragrances and flavorings for its fruity smell and taste
 - Iodopropynyl butylcarbamate – used as a common fungicide
 - n-hexadecanoic acid (palmitic acid) – major fatty acid component of lipids found in human cell membranes
 - Octadecanoic acid (stearic acid) – major fatty acid component of lipids found in human cell membranes
- We are currently following up with the authors with our questions and suggestions.

ADDITIONAL REFERENCES

RESOURCES ON INGEO PRODUCT SAFETY

- [Food Packaging Materials Compliance](#)
- [Gold Material Health Certification for Ingeo](#), Cradle to Cradle Products Institute
 - [Banned Substances List](#), Cradle to Cradle Products Institute
- [Prohibited Substances Policy for Ingeo](#)
- [Material Health & Safety Summary](#)



If you have any additional questions about Ingeo product safety, please contact us at inquiry@natureworkslc.com or visit our website at natureworkslc.com/material-health-and-safety.

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