



Integrating Toxicological Assessments in Material Selection for Apple Products

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Overview

A great deal of attention to detail and research go into choosing materials for Apple products to ensure workers, customers, and recyclers manufacture, use, and handle Apple products safely. The toxicological profile of materials is a key focus of Apple's material selection process during new product development.

All materials must meet Apple specifications on substances that are inherently hazardous, and undergo extensive materials characterization through testing to demonstrate conformity. In addition, Apple uses Full Material Disclosure (FMD), where material suppliers provide the entire chemical composition of homogenous materials, along with material characterization testing to enable Apple toxicologists to conduct comprehensive hazard and risk assessments. Leveraging rapid toxicological assessments ensures materials with unacceptable toxicological profiles are not permitted for use in Apple products.

Apple's Environmental Priorities

In 2013, Apple set three priorities for environmental responsibility to focus on areas where it could make the most impact. These include:

- Reducing Apple's impact on climate change by using renewable energy sources and improving energy efficiency in its products and facilities.
- Conserving precious resources by using more recycled and renewable content in its products, and increasing the supply of renewable resources.
- Identifying, developing, and utilizing safer materials in its products and processes.

Apple believes that reducing, restricting, and eventually eliminating the use of hazardous substances in materials is essential to ensure the safety of workers who manufacture its products, customers who use its products, and recyclers who handle its products at the end of the products' useful life. This commitment to the safety has driven Apple to lead the electronics industry in phasing out hazardous substances from its products.

History of Restricting Hazardous Substances

Apple initiated its program on safer materials in the early 1990s, when some heavy metals and polyvinyl chloride (PVC) were restricted in certain applications. At the time, Apple created a Regulated Substances Specification¹ that required its suppliers to abide by its restrictions on hazardous substances. Restrictions were increased steadily, with a major change occurring in 2009 when nearly all uses of brominated flame retardants (BFR) and PVC were eliminated.

BFRs were commonly found in polymers, including printed circuit boards, cable jacketing, and other electrical components. BFRs were eliminated because some were found to be persistent, bio-accumulative, and hazardous to humans and wildlife. BFRs were replaced with safer, less hazardous phosphorous-based and metal hydroxide flame retardants, or eliminated altogether through the use of natural flame-retardant materials such as aluminum.

PVC was primarily used in cable jacketing in power cords and data cables. It was eliminated due to several lifecycle concerns, including that highly toxic chlorinated dioxins can be generated during end-of-life processing. PVC was replaced with non-halogenated thermoplastic elastomers.

Removal of BFRs and PVC was challenging since safer alternatives were not readily available at the time. The largest obstacle was identifying a replacement to PVC in AC power cords, where strict safety standards favored PVC and created barriers to its elimination. Apple worked with multiple material suppliers and tested dozens of different formulations until the most suitable combination of performance and safety were achieved with lower toxicological and ecological risk than PVC. Apple then had to

persuade dozens of safety agencies around the world to allow it to certify the alternative materials. Millions of PVC-free power cords are in use today with Apple products.

In addition to restrictions on BFRs and PVC, Apple also phased out its use of mercury in display backlighting, arsenic in glass, and beryllium from connectors and springs. Each of these substances had undesirable toxicological properties and was replaced with safer materials.

While Apple's efforts to eliminate targeted hazardous substances improved the safety of its products, eliminating substances of concern one-by-one has its limitations. The approach tends to be reactive to public or regulatory pressure, and can include only a small subset of chemical substances used in commerce. It equally restricts use of all materials containing the targeted element or compound regardless of the actual risk from its use. Finally, it can prompt a simplified and misguided view that any replacement free of the targeted substance is a safer material, which has the potential of leading to regrettable substitutions.

To overcome these limitations, Apple implemented a comprehensive strategy that integrated risk assessments into material selection decisions during product development. Risk assessments include the identification of human and environmental health hazards of substances and estimating potential customer exposures.

Integrating Full Material Disclosure and Toxicological Assessments

Apple's current strategy for safer materials is built upon the fundamental premise that comprehensive action cannot be taken without a full understanding of the toxicological hazards and associated risks of chemicals in products. A necessary prerequisite for hazard and risk assessment is full knowledge of the chemical composition of materials used in products and the lifecycle exposures associated with those chemicals.

However, this approach is not standard practice for the electronics industry. Most brands do not have access to the material composition to estimate the toxicological risks of their products because no regulation stipulates a full disclosure of the product composition. In addition, composition is generally claimed as confidential information or trade secrets of the supplier. Even if the data were readily available, most brands lack infrastructure to collect, process, and make decisions based on that information.

Full Material Disclosure (FMD)

To understand the material composition of products, Apple launched a Full Material Disclosure (FMD) program with the ambitious goal of documenting the chemical composition of every homogeneous material in every component of Apple products. While this is not a novel concept, especially for the cosmetics and other health-focused industries, it is in its nascent stages for the electronics industry. Success depends on overcoming significant technological, business process, and intellectual property concerns.

Apple made significant investments in custom software tools and new processes to enable suppliers to document the material identity and chemical composition for every homogeneous material in Apple purchased parts and components. This was a complex undertaking that required millions of dollars of investment and nearly three years to implement. In addition, Apple faced significant challenges collecting the full material disclosure data from suppliers. Accurate disclosures require suppliers to track the composition of materials through multiple tiers of their own supply chain, which does not occur consistently. Moreover, some suppliers claim material identity and composition information as their intellectual property and are unwilling to disclose. Obtaining accurate and complete disclosures is a multiyear effort involving business redesign, education, and trust-building through multiple tiers of the supply chain.

To date, Apple has accepted more than 40,000 declarations for materials used in its products. Each disclosure goes through dozens of automated and manual checks for accuracy and completeness. Declarations that have known or suspected issues are sent back to the supplier for correction.

Toxicological Assessments

Following receipt of the full material disclosures, Apple utilizes a comparative chemical hazard assessment framework, such as Clean Production Action's GreenScreen® for Safer Chemicals², to assess the toxicological profile of each substance. This approach evaluates each chemical across 18 different human health and environmental hazard endpoints, including carcinogenicity, reproductive toxicity, and skin sensitization potential. It enables Apple toxicologists to make material use decisions based on the toxicological properties of the material and its application in the product. While toxicological evaluations require significantly more effort to administer than past approaches that restricted individual or entire classes of substances, Apple has found that comprehensive safety evaluations provide more meaningful data and context to material and product development decisions.

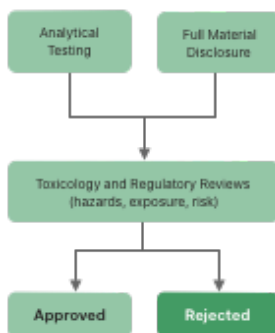
Evaluation of Process Chemicals

Apple's efforts have not been limited to materials that reside in the final product. For example, in 2014, Apple banned the use of benzene, n-hexane, and chlorinated organic compounds in cleaners and degreasers from its final assembly processes, and in 2016, Apple added toluene and N-methyl-2-pyrrolidone to its regulated substances specification. The scope of the manufacturing process restrictions for benzene, brominated organic solvents, chlorinated organic solvents, methanol, n-hexane, and ozone depleting chemicals were expanded to no intentional use for all manufacturing process chemicals in the 2021 update of its regulated substances specification.

Additionally, Apple has documented the chemical composition of key process chemicals, such as cleaners and degreasers, used at Apple's contract final assembly manufacturing sites. While these chemicals do not reside within the final manufactured product, an understanding of these substances was essential to ensure the safety of assembly workers. Apple evaluated the constituents of each material according to the GreenScreen® framework and similar approaches. It was found that only a very small fraction of solvents used in cleaners and degreasers across all final assembly sites were classified as a chemical of high concern. Although proper exposure and safety controls were in place, Apple aggressively identified and implemented safer alternatives for each of these in order to mitigate potential future risk. Classification of solvents and degreasers according to hazard was an effective prioritization tool for finding safer materials.

The inclusion of a hazardous substance in a regulated substances specification is not sufficient to effectively restrict its use. Apple conducts extensive onsite assessments evaluating chemical uses, the manufacturing processes, and occupational exposure risks to ensure the highest standards of chemical management practices at its suppliers. These engagements are led by industrial hygienists and supported by toxicologists. During these engagements, Apple maps chemical usage, identifies potential health and safety risks, educates supplier staff on sound practices, and partners to evaluate safer alternatives to reduce and replace chemicals of concern. Hazard evaluations are conducted on all newly identified substances. In 2019, Apple implemented Chemical Safety Disclosure (CSD), an initiative that requires suppliers to provide information on the chemicals used in Apple manufacturing processes, to report practices in place to ensure compliance with occupational health and safety regulations and Apple requirements, and to support initiatives to advance the adoption of safer, environmentally preferable alternatives.

Apple Watch Case Study: Integrating Toxicology into Material Selection



Products in prolonged skin contact, such as Apple Watch, require more rigorous controls on material safety. With customers often wearing Apple Watch for more than 12 hours per day, every day, exposure is far greater than typical consumer electronic devices. Wearable technology potentially imparts higher risks to customers, increasing the importance of robust material selection decisions.

Recognizing the increased risk to its customers, Apple implemented more stringent processes to control materials in prolonged skin contact by fully integrating toxicological risk assessments during the material selection process with the design of new products. Apple's process involved three steps:

1. Implementation of a regulated substances specification specific to products with materials in prolonged skin contact
2. Material characterization testing to objectively evaluate conformity to the specification and characterize leachable substances for skin contact risks
3. Toxicological hazard and risk assessments based on full material disclosure to identify additional risks

A detailed description of each step is provided in the following sections.

Step 1: Publication of a regulated substances specification for materials in prolonged skin contact

All materials used in Apple products, including materials in prolonged skin contact, must comply with the Apple Regulated Substances Specification (069-0135). Apple created an additional specification restricting certain hazardous substances in wearable devices and non-wearable products with materials in prolonged skin contact, as consumer exposure is higher in these categories of products, and regulatory limits are in general not available or may not be sufficiently protective for prolonged skin contact. It places materials into categories, for example, metals, plastic, glass etc., where each has an independent test plan for targeted substances. The specification has a focus on dermal irritants and sensitizers. Irritants and sensitizers were highlighted because customer skin reactions are the most commonly reported health effect for products in prolonged skin contact, such as jewelry.

Apple also modified its approach to limiting the concentration of hazardous substances. In some instances, restrictions for a given substance have two different thresholds: (i) maximum allowable limit (MAL), and (ii) threshold for toxicological review (TTR). If a substance exceeds the MAL, an analysis is done to confirm whether it exceeds any global regulatory restriction or potentially compromises customer safety, either of which leads to a rejection of the material. If the material has a substance with a concentration lower than the MAL but higher than the TTR, an evaluation by Apple toxicologists is

triggered. This review is necessary because the specification is application blind, and cannot reflect exposure. Therefore, a material's approval will depend on the expected exposure to the substance and the relevant toxicological endpoint of concern. This split threshold allows for more precision on evaluating safety of exposures to chemicals based on the relevant toxicological endpoint of concern under the use conditions of the material within the product.

The prolonged skin contact specification is available to material suppliers, and the material suppliers can voluntarily conduct testing to demonstrate compliance to the prolonged skin contact specification requirements. Nevertheless, all prolonged skin contact materials undergo material characterization testing by Apple to validate compliance to the specification.

Step 2: Materials characterization testing

Materials characterization testing is an essential process to ensure compliance to the prolonged skin contact specification and to uncover any hazardous substances that are present but not expressly listed in the specification. Apple program managers advise product design teams on the requirements for safety and environmental initiatives. The program managers ensure the proper and adequate tests are completed. In instances where there would be safety or non-compliant concerns, these are promptly communicated to the suppliers for correction.

Materials characterization is broken down into the following sub-steps:

1. Measure the concentration of specific substances covered by Apple's prolonged skin contact specification, and
2. Extraction testing in artificial sweat and other appropriate solvents to screen for substances that can potentially leach out of the material. This process is modeled on extractable testing typically conducted by the medical device industry. In the case of metal components, the leach rate of metals that are potential skin sensitizers (e.g., nickel and cobalt) are measured in artificial sweat.

Materials characterization testing is specific to the material type, with some requiring tests for more than 180 regulated substances. To account for other potential substances of concern, screening for organic compounds is conducted to supplement the targeted testing. Testing is conducted both in third party labs and Apple's internal lab. Since 2006, Apple's internal lab has grown to 40 times its original size, adding state of the art equipment to characterize materials, including:

- Inductively Coupled Plasma-Mass Spectrometry (ICP-MS)
- X-ray Fluorescence Spectroscopy (XRF)
- Laser-induced Breakdown Spectroscopy (LIBS)
- Combustion Furnace Ion Chromatography (C-IC)
- High Performance Liquid Chromatography-High Resolution Mass Spectrometer (HPLC-HRMS)
- Gas Chromatography-Mass Spectrometry (GC-MS)
- Liquid Chromatography-Mass Spectrometry (LC-MS)

While Apple continues to rely on third party labs to conduct verification testing, in-house test capability has increased the speed of evaluations and internal know-how which are important to keep up with the rapid pace of new product development. Apple analytical chemists are continuously developing methods to analyze for newly regulated or potentially hazardous substances to determine their impact and eventually help reduce or eliminate them from products.

Toxicologists use the testing results to conduct risk assessments for material selection. Acceptable exposure levels are either obtained directly or derived from the scientific literature. For substances with data gaps, read-across from structurally-related compounds as well as predictive computational models are implemented. Appropriate and conservative uncertainty (safety) factors are incorporated into the derivation of acceptable exposure levels to account for uncertainty inherent in the available toxicological

data. The acceptable exposure level is then compared to an estimated consumer exposure level under conservative and appropriate use conditions of the material. If the consumer exposure level exceeds the acceptable exposure level, the material is not approved for use.

While this evaluation is cost and labor intensive and requires resources not usually found in the electronics industry, it is the most essential step to objectively and comprehensively evaluate safety. Characterizing safety of materials without knowing the full composition requires a battery of testing for substances of concern combined with supplier statements. Higher quality assessments can be completed if the full chemical composition is known.

Step 3: Toxicological hazard and risk assessment based on Full Material Disclosure

In the third step, toxicological assessments are conducted based on the full material disclosure provided by the raw material supplier. This enables an evaluation of the hazards and risks associated with the material based on the declared substances and concentrations. In addition, it has the benefit of helping focus material characterization testing on potentially problematic areas and to rapidly determine if well-known hazardous substances are present in the formulation.

Apple has conducted hundreds of toxicological hazard and risk assessments with this approach for materials. In cases where material suppliers were unwilling to provide Apple with a full material disclosure, an “escrow” model was used where the supplier disclosed the composition to a third-party toxicology consultancy, which then completed a hazard evaluation for Apple. The hazard evaluation provided to Apple redacted the chemical composition, leaving only the hazard information. While this approach helps to overcome supplier concerns about the protection of trade secrets and confidential business information, direct access to the composition has significant benefits in material selection decisions.

Material Safety Assessments

Material safety decisions are made by Apple toxicologists based on the aforementioned three steps. All materials intended for use in a prolonged skin contact applications are required to follow this process before they are approved. The process is designed to be rapidly executed with redundancy to ensure determinations can be made within the timelines associated with new product development. Lastly, it also avoids ethical concerns associated with *in vivo* testing.

While the majority of testing is focused on individual materials or components in order to have the greatest specificity and isolate for variables, testing is also conducted on assembled units and products to account for material interactions and variability in assembly processes. Testing is also conducted on products that have undergone simulated life testing, in the event expected use has an impact on safety.

Finally, Apple investigates all incidents of reported skin reactions with board-certified dermatologists to determine the condition and establish causation. In addition, where feasible, failure analysis is conducted to identify the root cause and enable improvements in product design.

Conclusion

A great deal of attention and research goes into selecting materials for all Apple products. Apple’s process relies upon a combination of tools to evaluate and ensure exposure to hazardous chemicals is prevented or remains below conservative safety thresholds. The combination of substance restrictions, full material disclosure, comprehensive analytical testing, and use of toxicological risk assessments provides an effective means of ensuring workers, customers, and recyclers can manufacture, use and handle Apple products safely.

¹"Apple Regulated Substances Specification, 069-0135," Apple Inc., Cupertino, USA, Apple Inc., 2021 [Online]. Available: https://www.apple.com/environment/pdf/Apple_Regulated_Substances_Specification_March2021.pdf.

²Clean Production Action, "GreenScreen® for Safer Chemicals Hazard Assessment Guidance, Version 1.3 (1e)", 2016.

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