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Are Hoses Used for Food and Beverage Transfer Applications Really Safe for Consumers?

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The food and beverage processing industry uses a variety of hoses to transfer liquids and foods from tank to tank, from pipes to tanks and trucks, and virtually in any loading and transfer applications. Currently, hoses are made from Plastics, Rubber, Fluoropolymers and/or Silicone materials. To achieve the desired performance, the hose is commonly constructed with a relatively complicated structure of several layers. Common structures include an inner liner (in direct contact with food), one or more reinforcement layers, and an outer jacket layer to reduce wear and tear, sometimes resulting in upwards of 7 or more layers.

It is understood in the hose industry that the chemicals from the food contact layer may migrate into the transfer media during the fluid transfer process and are regulated by FDA Additive Regulation 21 CFR 170-189. When the level of migration is above a certain threshold, the chemicals may adulterate the food and potentially pose adverse health risks to the consumers. However, is testing only the food contact layer all that is needed to properly assess the risk to the consumer? From testing this single layer, can it be concluded that the entire hose is safe for the consumer? This question is what has prompted additional study from the Saint-Gobain team.

***Figure 1**: Food and Beverage Hoses*

How are Food and Beverage hoses currently regulated in the USA?

The U.S. Food and Drug Administration (FDA) established the regulatory requirements for food contact substances (FCS) in section 21 CFR Parts 170-189. These Parts of the Regulations stem from the definition of a "food additive" under the U.S. Federal Food, Drug and Cosmetic Act (FFDCA) Section 201(s). A food additive is defined under the act as any substance that may reasonably be expected to become a component of food as result of its intended use (Food and Drug Administration, 2020). The chemicals from hoses which migrate into food at "significant" levels are considered "food additives" and should be subjected to the FDA's premarket clearance requirements, meaning they are subject to applicable Food Additive Regulations, an effective Food Contact Notification, or a Threshold of Regulation exemption letter, etc. The FDA also allows exemptions to Food Additive Regulations if the substances are Generally Recognized as Safe (GRAS) or prior-sanctioned by FDA for a particular use (Food and Drug Administration, 2020). For a chemical which is not cleared by the FDA, the threshold of migration is 10-50 ppb and it may even be a lower limit when there are special toxicological concerns; for example, if the chemical is carcinogenic, mutagenic, and toxic to reproduction. The manufacturers are required to establish a suitable U.S. food-contact status for the food contact substances which could potentially migrate into food. However, the current understanding within the Food & Beverage industry is to focus solely on the food contact layer while ignoring any migration from non-food contact layers (nFCLs), which could pose a health risk to the consumer.

What is missing in the compliance process to protect the consumer?

A study by Saint-Gobain has observed that chemicals from non-food contact layers of the hose could potentially migrate into the food through the food contact layer by testing a multilayer hose product. An inner white rubber layer was fully submerged in a simulant at 60°C for three weeks, with samples taken at various times throughout the soak. The multilayer hose was also filled with the same simulant at 40°C and allowed to soak for the same time periods. Figure 2 shows the resulting gas chromatography result from the analysis of both simulants after soaking. The data shows the chemicals contained in the non-food contact layer (i.e. white rubber in Figure 2 (top)) were also observed in the food simulant (95% ethanol), which has been put in contact with the hose at 40°C that were not previously present in the liner material (Figure 2 (bottom)).

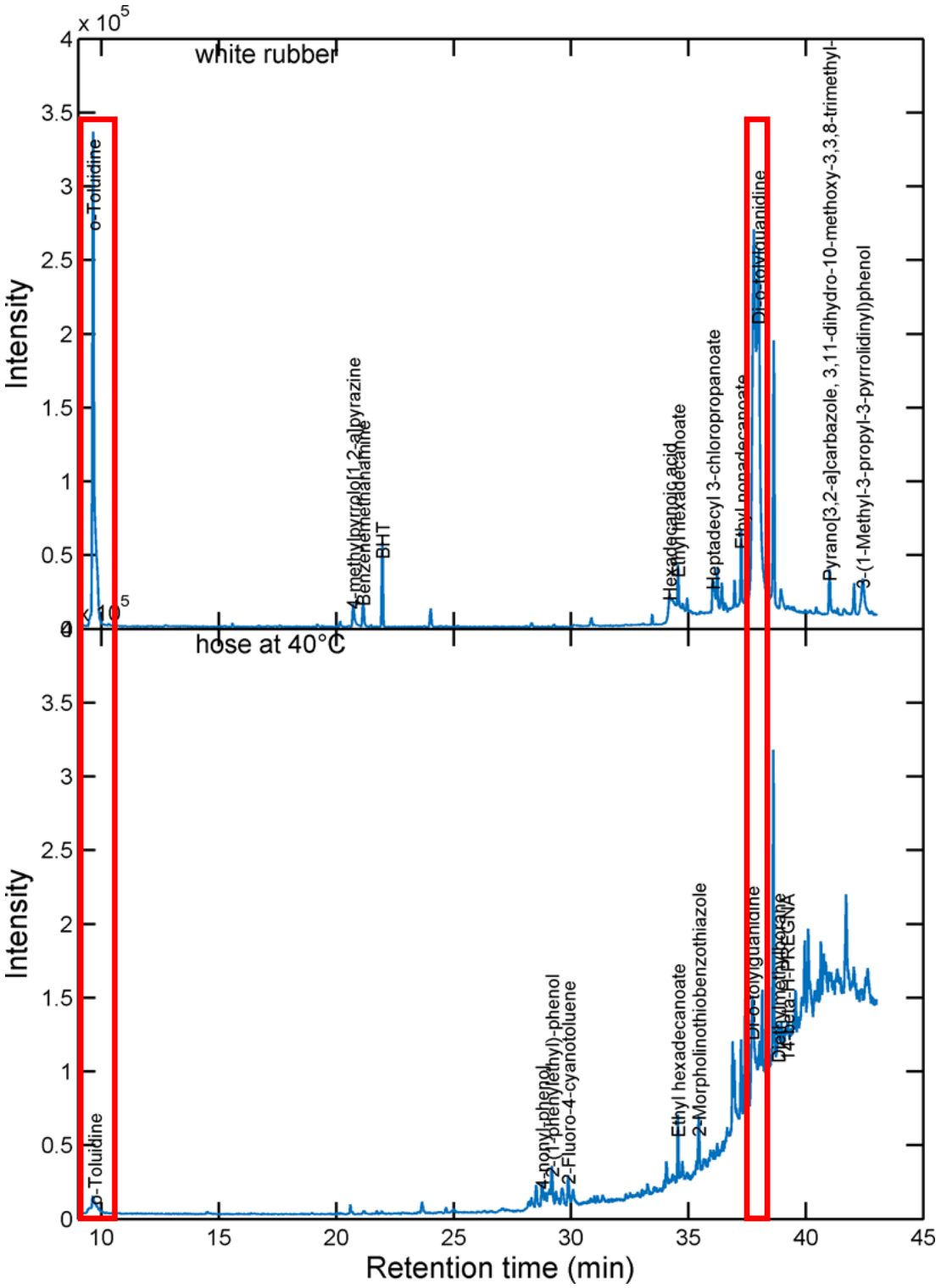

***Figure 2**: Gas Chromatograms of a migration profile of components from a non-food contact layer (top) and from the simulant in contact with the hose (bottom)*

In fact, the migration could happen at a much earlier time even before the hose is being used. It starts immediately upon the manufacture of the hose when the layers are assembled together and in direct contact with each other. When multiple layers are placed in contact, migration will reach equilibrium until the chemicals are well dispersed within each layer. Since the food contact layer is constantly being "washed" by the food transfer media, the migrants may end up in the food, which implies that even before use, the food contact layer has already been contaminated by the non-food contact layers. Over time, eventually the chemicals will leach out of the hose into the transfer media, however this is highly dependent upon temperature, volume, type of fluid, hose thickness, etc.

This type of indirect mass transfer phenomena is typically not considered by the hose industry and has not been addressed clearly by the FDA Regulations. We have also not seen many technical and product publications on the chemical migration between non-contact (liner) layer and inner layer(s) in F&B hose applications. It is understandable that hose manufacturers might not intentionally select low toxic, or non CMR (carcinogenic, mutagenic and toxic to reproduction) substances to formulate the non-food contact layers. So, the hose product being sold on the market may already have a contaminated liner with CMR substances prior to use.

Saint-Gobain has been extremely cautious about product safety and fit-for-use, particularly when products and solutions are offered to critical applications, such as food contact, pharmaceutical applications, medical devices, etc. In particular, within food and beverage applications, if it is known that the potential indirect migration poses an adverse health effect to the consumer, the risk must be mitigated. To address the risk, Saint-Gobain has developed a tiered approach to be able to assess the migration of chemicals from the non-food contact layers by considering both the toxicity profile of the substance and its migration level at the customer use conditions. (Figure 3).

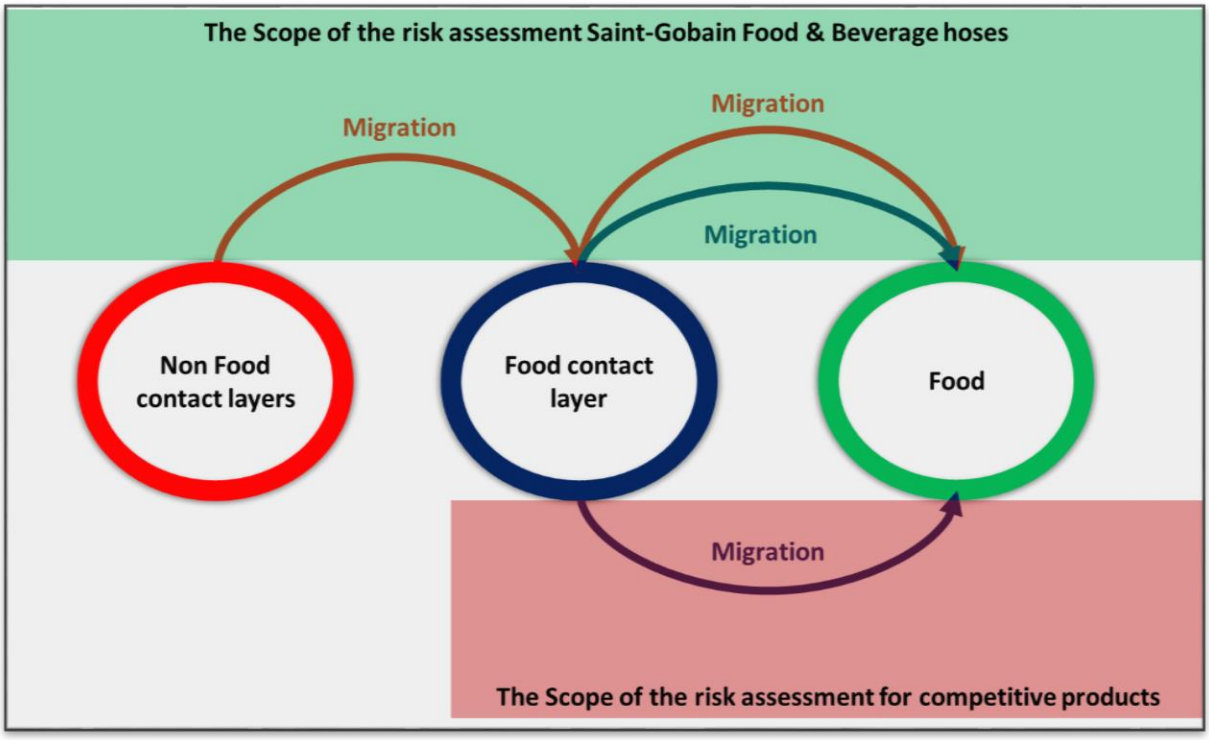

***Figure 3**: Risk assessment scope of Saint-Gobain hose products*

Typical testing for FDA food contact compliance involves using a plaque of the food contact layer only, and testing it for extraction levels over a period of time in various media (i.e., distilled water, n-Hexane, etc. in 21CFR 177.2600) as indicated by the FDA Regulation. Therefore, as a result, many hose manufacturers on the market could claim food contact compliance for their hose products, though if one looks closely, it is only for the food contact layer. As demonstrated in Figure 2, migration through layers is possible and over time will impact the transfer media in the hose product.

***Figure 4**: Cross section of Saint-Gobain Life Sciences Versilon™ XFR hose*

Saint-Gobain Versilon™ XFR is the first hose to be fully FDA food contact compliant

To benchmark Versilon™ XFR against current hose offerings, we have chosen and performed migration testing on a hose which has only the inner liner that is claimed to be compliant with the FDA Food Additive Regulations (Figure 5). Migration testing was performed at 60°C using a food simulant of 95% ethanol by filling and capping the hose. A chemical substance was measured at a level up to 6.67 ppm which is not cleared by FDA or EU food regulations, and is significantly above the threshold proposed by FDA (10-50ppb or even lower). Through further research, it was found that this substance originated from the non-food contact layers. Therefore, by claiming the inner liner as FDA compliant of such product could mislead the consumer that the product is safe to use for food contact applications.

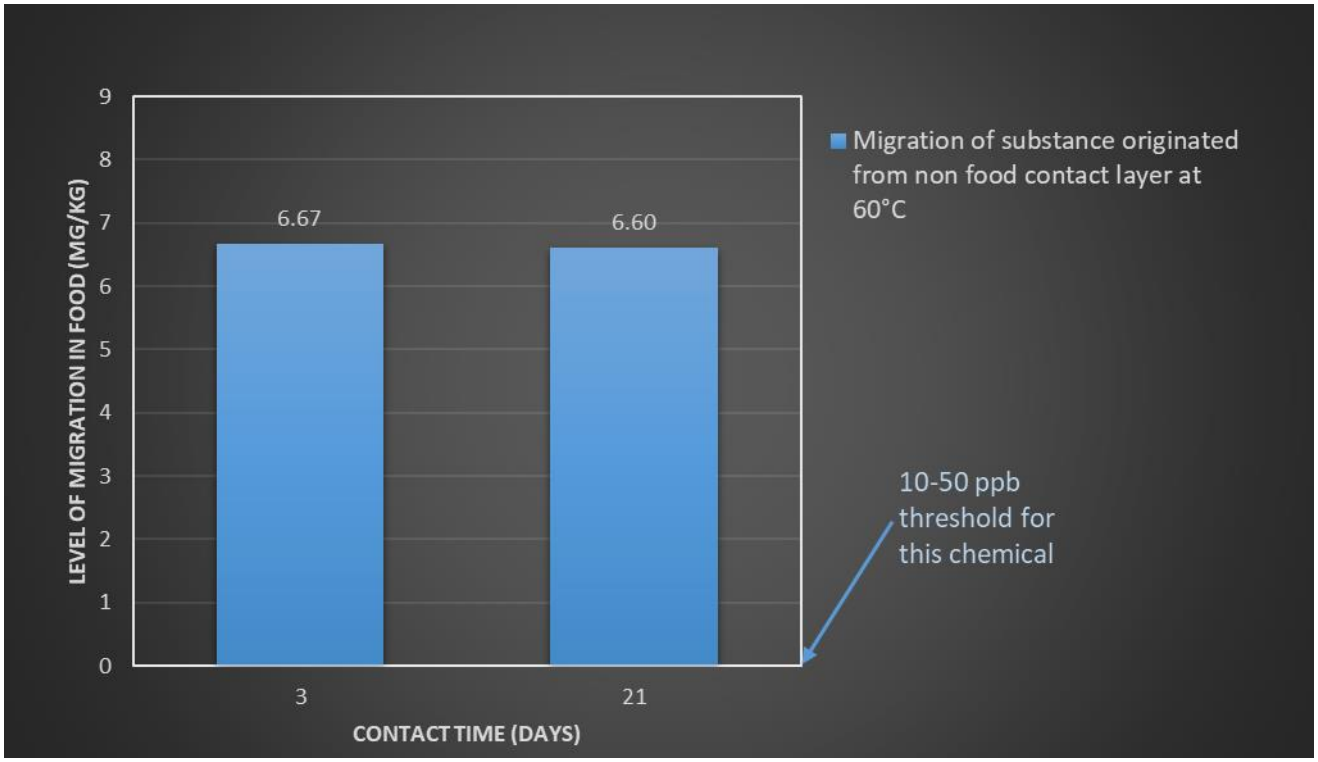

***Figure 5**: Substance migration level from a multilayer hose available on the market with only the inner liner that is compliant with FDA Food Additive Regulations*

At the same contact temperature, the migration level of chemicals from the non-food contact layer of the Versilon™ XFR hose shows a promising low value. This is a different chemical substance than what was observed in the previous figure and has been cleared by many food contact regulations globally, including FDA regulations, however the threshold was not provided. Therefore, the specific migration limit of 2.5ppm was adopted from the EU food contact regulation (EU) No 10/2011 (see Figure 6). The migration value of the product is much lower than the proposed threshold, and provides assurance that Versilon™ XFR hose is safe to be used for food contact applications, delivering peace of mind for the end user.

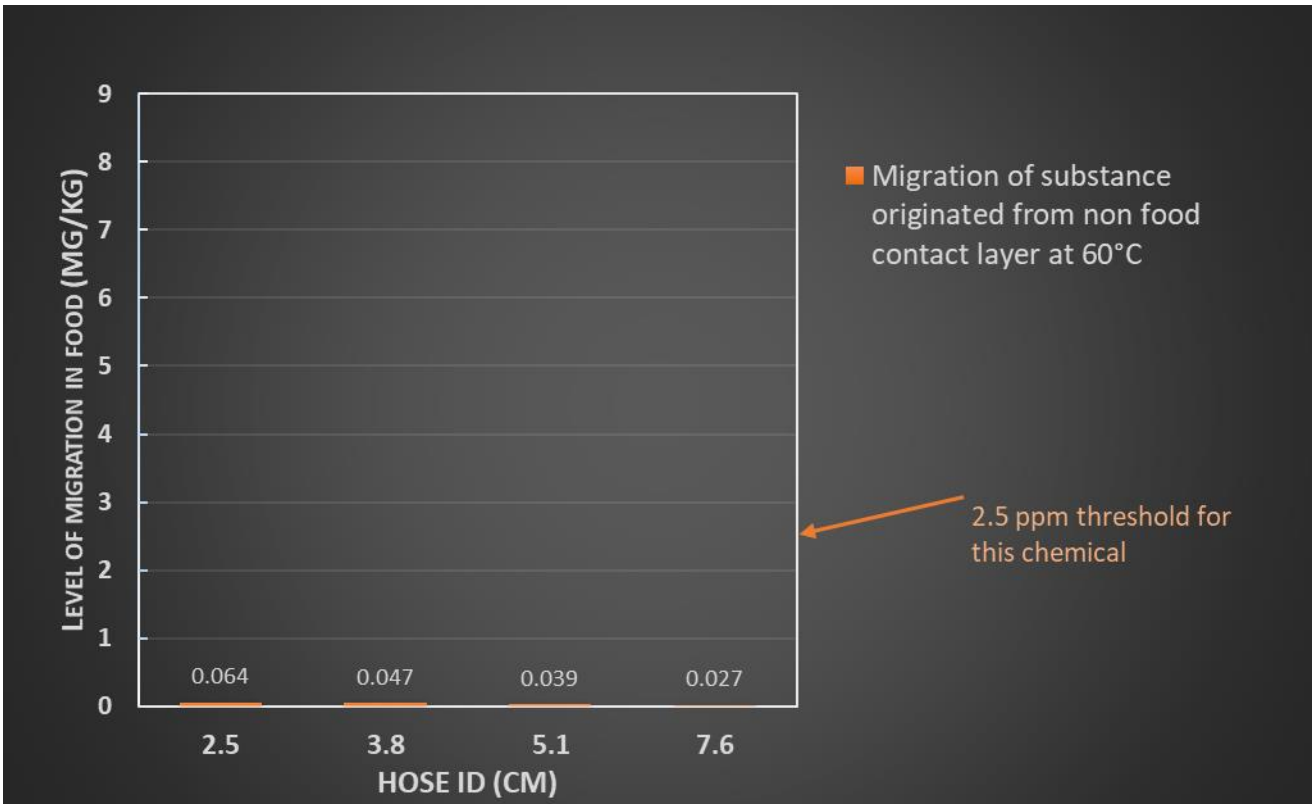

***Figure 6**: Substance migration level in Versilon™ XFR hose*

The Saint-Gobain Solution: Versilon XFR – a unique hose with full FDA compliance from Cover to Core

With all the technical work that has been done, we are proud to recommend Versilon™ XFR hose to our food and beverage customers as a unique product on the market. As of the date of writing this document, all of its layers have been evaluated for FDA food contact compliance and Versilon™ XFR is the first fully FDA food contact compliant hose. Saint-Gobain believes in preserving the fluid integrity and aims to mitigate risk wherever possible. This peace of mind for end users and distributors is priceless! Safeguarding the integrity of the food is paramount and as a result the hose selection is critical. Choosing the right supplier to provide high performance and high quality solutions will help insure that the right hose is used for the right application. With comprehensive design capabilities and material science know-how, Saint-Gobain can help customers achieve their food and beverage transfer performance and safety goals.

Saint-Gobain's food and beverage transfer solutions and products are designed to support critical performance requirements. With our extensive testing capabilities, R&D centers, application and regulatory compliance expertise and flexible, global manufacturing footprint – our customers can successfully address any challenges and achieve their performance goals.

About Saint-Gobain

Saint-Gobain designs, manufactures and distributes materials and solutions which are key ingredients in the wellbeing of each of us and the future of all. They can be found everywhere in our living places and our daily life: in buildings, transportation, infrastructure and in many industrial applications. They provide comfort, performance and safety while addressing the challenges of sustainable construction, resource efficiency and climate change. With €42.6 billion in sales in 2019, Saint-Gobain operates in 68 countries and has more than 170,000 employees.

Works Cited

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