Toxicological Risk Assessment Summary – Direct Materials for Tobacco Products

Philip Morris International

1 General Assessment Principles

The materials and ingredients used as Direct Materials (DIM) (see section 2) in tobacco products (in this document, tobacco products include both combustible cigarettes and heated tobacco products), are assessed according to the company quality standard and subjected to rigorous toxicological risk assessment with the objective of assessing that product modifications do not result in new hazard for human health or an increase of the inherent toxicity of the products. The toxicological risk assessment generally follows the four-step analytic process for human-health risk assessment (National Research Council Committee on Risk Assessment of Hazardous Air Pollutants, 1994), which includes hazard identification; dose-response assessment; exposure assessment; and risk characterization. For PMI's toxicological risk assessment of combustible cigarettes and heated tobacco products modifications, the type and significance of the product modification, such as the intended use of the DIM, determines the amount of information required to complete the assessment. The data thus acquired ranges from a literature-based assessment of the disclosed substances of the DIM in their unburnt/non-heated form to testings on the DIM up to assessing the final product design constructed with the respective DIM mainly through targeted aerosol/smoke chemistry to demonstrate no negative impact on performance.

Although inhalation data are preferred and prioritized to derive reference dose (e.g., acceptable daily exposure), risk assessment can be supported by other data based on weight-on-evidence approach. When appropriate, modifying factors accounting for differences in species, route of exposure, duration of exposure, and pharmacokinetics are incorporated into the risk assessment. Such an approach is aligned with the risk assessment approaches used by others (EPA, 1993, Schenk et al., 2014). In addition, when data are scarce, the Threshold of Toxicological Concern (TTC) concept is used. TTC is a concept whether or not there are chemical-specific toxicity data, below which there would be no appreciable risk to human health (Kroes et al., 2005). The TTC principle is used by the European Medicines Evaluation Agency to assess genotoxic impurities in pharmaceutical preparations and has been endorsed by both the World Health Organization International Program on Chemical Safety for the risk assessment of chemicals and the European Union Scientific Toxicology, Ecotoxicology and the Environment (Kroes et al., 2005).

In addition, further analysis may be included (e.g., chemistry analysis of the heated/burnt materials coupled by literature and in silico analysis). For example, Volatile Organic Compounds (VOC) analysis (e.g., at 100°C) and pyrolysis analysis (e.g., at 500°C or 1000°C) are conducted to evaluate the thermal degradation profile following heating or burning. Furthermore, depending on the foreseen impact of the change to the product, aerosol or smoke chemistry analysis may be conducted.

2 Examples of Direct Materials used to manufacture tobacco products

2.1 Adhesives

In the manufacturing of tobacco products, adhesives have various functions. It is used to secure the paper surrounding the tobacco rod; it is used within the filter in various places; it is used to secure the plug wrap to the filter (referred to as the anchor adhesive); it is used to adhere plug wraps to the filter (referred to as the filter lap seam adhesives); and it is used to adhere the tipping paper to the plug wrap (referred to as the tipping adhesives).

2.2 Base Tipping Papers and Inks

The base tipping paper is used to hold the filter and tobacco rod together. This non-porous paper joins the filter plug and the tobacco rod by completely covering the plug and overlapping the tobacco rod by several millimeters.

The finished tipping paper is printed with decorative lines and brand logo. The inks used to print these attributes are collectively called tipping inks. Different printing technologies can be used (e.g., gravure printing or hotfoil stamping). Each technology may use specific ink formulations.

2.3 Filter Materials

The main purpose of the filter is to trap the particulate or gas vapor material generated by either the combustible cigarette or the heated tobacco product. In addition to the filtration function, the filter may serve as a mouthpiece to prevent direct contact between the tobacco rod and the mouth.

2.4 Flavoring Capsules

Such flavoring capsules are embedded in the filter where the consumer can crush them at any chosen time and release the aromatic liquid causing the aerosol to have specific flavors.

2.5 Papers and Wrappers

Such wrapper is used to hold the filter tow tightly together (to achieve a firm and cohesive filter rod).

In the combustible cigarettes, cigarette papers are a complex part of each individual cigarette design. While the cigarette paper is only about 5% of the total tobacco rod weight, it influences the static smolder rate, ventilation, puff count, pressure drop and yield. Cigarette paper is composed of inorganic filler and cellulosic fiber. The most common inorganic filler is calcium carbonate. Most cigarette papers are white. Since no whiteners are added during manufacture, the filler and the fiber bleaching determine the whiteness of the finished paper. The filler holds the fibers apart, creating pores within the paper structure. Air permeability is a key paper specification governing smoke yield that results from the amount and size of the filler particles and the density (basis weight) of the paper sheet. Monogram inks can be used as decorative brand identifiers printed on the tobacco rod. Generally, this print occurs close to the filter although in some brands the monogram starts at the filter end and extend towards the end of the tobacco column.

The main function of plug wrap is to hold the filter tow tightly together to achieve a firm and cohesive filter rod and to hold this rod to the tobacco column of the cigarette.

In the heated tobacco stick making process, the plug wrap is pre-applied with adhesive then transported on a belt where the filter tow is fed onto it. The belt, plug wrap, and tow are then formed in a cylinder by rolling the edges of the belt inward. The edges of the plug wrap are glued together, and the rods are cut into their desired lengths. The plug wrap maintains the compression on the tow band; accordingly, such a paper must be extremely strong.

2.6 Susceptors (applicable for heated tobacco products only)

The susceptor is used to allow for the transfer of heat to the tobacco to generate an aerosol. The susceptor is placed in the middle of the tobacco plug during manufacturing of the tobacco plug

part of the tobacco stick. The susceptor generates and propagates the heat once it is exposed to a magnetic field generated by a coil module.

3 References

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NATIONAL RESEARCH COUNCIL COMMITTEE ON RISK ASSESSMENT OF HAZARDOUS AIR POLLUTANTS 1994. *Science and Judgment in Risk Assessment.* Washington (DC): National Academies Press (US) Copyright 1994 by the National Academy of Sciences. All rights reserved.

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