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1 PRINCIPLES OF OPERATION

1.1 Formulations and Intended Function of Each Ingredient

ZYN® is a 0.4-gram tobacco-free sealed pouch containing nicotine bitartrate dihydrate and food-grade stabilizer, fillers, pH adjusters, sweetener, and flavorings. ZYN pouch material consists of (b) (4), and (b) (4). ZYN is manufactured in 10 flavors, each at 3-mg nicotine and 6-mg nicotine strengths.

The formulation of each strength of ZYN across all flavors uses the same ingredients, with the exception of the flavor-specific components. The pouch material is identical for both strengths across all flavors. The ingredients common to all flavors of the ZYN finished product (3 mg and 6 mg) and the intended function of each ingredient is presented in Table 1. The specific flavors used for each of the 10 flavor formulations are presented in Table 2. Detailed formulations with the specific amounts of each ingredient are listed in [Section G.3 Product Manufacturing and Controls Summary, Section 1.4](#). Details about Pouch Material can be found in [Section G.4, Product Composition Summary, Section 1.1](#). Information on the flavor manufacturers is found in [Section G.3 Product Manufacturing and Controls Summary, Section 1.2](#).

Table 1 ZYN Finished Product Common Ingredients and Their Intended Function

Ingredient	Unique ID	CAS Number	Function
Acesulfame K	(b) (4)	(4)	Sweetener
(b) (4)			Processing aid
Hydroxypropyl cellulose			Stabilizer
Maltitol			Filler
Microcrystalline cellulose			Filler
Nicotine bitartrate dihydrate			Other (key ingredient)
Pouch material			Fiber
Sodium bicarbonate			pH adjuster
Sodium carbonate			pH adjuster
(b) (4)			Processing aid

Source: [Section G.3 Product Manufacturing and Controls Summary, Section 1.4](#).

CAS=Chemical Abstract Service; NA=not applicable.

Table 2 ZYN Finished Product Flavor Components for Each Formulation

ZYN Product and Strength (Unique ID KY; SE)	Flavor Component	CAS Number
Cool Mint 3 mg (900510; 8105) Cool Mint 6 mg (900520; 8106)	(b) (4)	(4)
Peppermint 3 mg (901510; 8107) Peppermint 6 mg (901520; 8108)		

ZYN Product and Strength (Unique ID KY; SE)	Flavor Component	CAS Number
<div> <div>Spearmint 3 mg (902510; 8109)</div> <div>Spearmint 6 mg (902520; 8110)</div> </div>	(b)	(4)
<div> <div>Wintergreen 3 mg (903510; 8111)</div> <div>Wintergreen 6 mg (903520; 8112)</div> </div>		
<div> <div>Citrus 3 mg (907510; 8122)</div> <div>Citrus 6 mg (907520; 8123)</div> </div>		
<div> <div>Coffee 3 mg (904510; 8124)</div> <div>Coffee 6 mg (904520; 8125)</div> </div>		

ZYN Product and Strength (Unique ID KY; SE)	Flavor Component	CAS Number
Cinnamon 3 mg (906510; 8128) Cinnamon 6 mg (906520; 8129)	(b) (4)	(4)
Smooth 3 mg (914510; 8134) Smooth 6 mg (914520; 8135)		
Chill 3 mg (920510; 8136) Chill 6 mg (920520; 8137)		
Fresh 3 mg (921510; 8140) Fresh 6 mg (921520; 8141)		

Source: (b) (4)

(b) (4)

CAS=Chemical Abstract Service; ID=identification; KY=Owensboro, Kentucky manufacturing site; NA=not applicable; SE=Kungälv, Sweden manufacturing site.

1.2 Packaging Components and Intended Function of Each Component

ZYN is manufactured as a quantity of 15 pouches contained in a 21 Code of Federal Regulations 177.1520(c)-compliant polypropylene (PP) can, incorporating a certified PP child-resistant safety lid. The consumer opens the can by breaking the perforation of the label, twisting the lid to align the top and bottom arrows on the can, and lifting the lid straight off. The primary container (can and lid) is designed to provide child-resistance while allowing adults to access the product. For details of the ZYN finished product container, including diagrams, refer to [Section G.4 Product Composition Summary, Section 1.3.1](#). Refer to [Section G.3 Product Manufacturing and Controls, Section 2.9](#) for details of the child-resistance assessment of the package.

For shipping and retail sale, ZYN cans are wrapped in rolls containing five cans per roll, using low-density polyethylene shrink film. ZYN rolls are packed in corrugated cardboard cases containing 18 rolls per case, for a total of 90 cans per case. The case is assembled with polyvinyl acetate glue and sealed with PP sealing tape. The secondary packaging of the roll shrink-wrap, in conjunction with the can, protects the product from environmental contamination during shipping and storage. The tertiary container (case) provides additional protection of the product during transport. The rolls and individual cans are appropriately labelled and maybe sold individually to the end user (consumer). Refer to [Section G.4 Product Composition Summary, Section 1.3.2](#) and [Section 1.3.3](#) for a complete description of the secondary and tertiary container systems, respectively.

1.3 Product Use

The consumer places the ZYN pouch between the upper lip and gum. The pouch is held between the lip and gum for up to 60 minutes and then discarded. When used as directed, the pouch allows the nicotine to dissolve in saliva and be absorbed through the mucous membrane of the mouth.

The instructions for product use are included on the can side label and the roll label:

1. Break perforation on side label.
2. Twist lid, align arrows, and lift.
3. Place in upper lip, enjoy up to 1 hour.

A representative label for the ZYN product use is presented in Figure 1.

Figure 1 ZYN Product Use Labeling



Source: [H.1.3.1 Diagram\(s\) Showing Product Use](#)

1.4 Consumer Modification

1.4.1 Altering the Quantity of Nicotine

ZYN 3-mg strength contains (b) (4) mg nicotine bitartrate dihydrate and ZYN 6-mg strength contains (b) (4) mg nicotine bitartrate dihydrate. These quantities are calculated to achieve a nicotine content of 3 mg and 6 mg, respectively.

Swedish Match does not reasonably expect consumers to be able to modify the nicotine content of ZYN pouches, based on the granulated form of the pouch contents.

1.4.2 Manipulating the Design

Potential modifications could include opening the pouch and attempting to consume the pouch contents through means inconsistent with the labeling. Out of (b) (4) Swedish Match call center contacts related to product manufacturing and potential adverse events between October 2017 and July 2019, only (b) (4) (5.1%) were the result of improper use of ZYN. (b) (4) (3.6%) of these involved swallowing of the pouch intact. (b) (4) contacts (0.4%) were the result of opening the pouch and attempting to metabolize the ZYN formulation in an inappropriate way, such as ingestion, inhalation, or combustion. Due to the design, Swedish Match considers the potential for consumer modification of ZYN to be low.

1.5 Product Variations

The minimal variations between the ten flavors and two strengths of ZYN are described in Section 1.1. Both the 3 mg and 6 mg strengths of each flavor contain the same ingredients and differ only in the amount of nicotine bitartrate. The various flavors of ZYN contain the same pouch and common ingredients and differ only in the flavor components.

1.6 Assessment of Product Risk

Refer to [Section G.5 Nonclinical Evaluation Summary](#) for the assessment of product risk.