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## 1 INGREDIENTS

The ingredients for each flavor of Swedish Match ZYN finished product are presented in the following sections. In addition to nicotine bitartrate dihydrate, ZYN contains only food-grade ingredients. The ingredients of the pouch contents include the following:

- Nicotine bitartrate dihydrate
- Hydroxypropyl cellulose (stabilizer), which is used to maintain pouch consistency
- Microcrystalline cellulose, maltitol, and gum arabic (fillers), which are used to add bulk to each pouch
- Acesulfame K (sweetener), which is an artificial sweetener
- Sodium carbonate and sodium bicarbonate (pH adjusters), which are used to adjust pH levels
- Food-grade flavorings, which are used to enhance the taste of each pouch

### 1.1 Composition of ZYN Finished Product

The ingredients common to all flavors of ZYN finished product (3 mg and 6 mg), the Chemical Abstracts Service (CAS) numbers, and the ingredient function are presented in Table 1. The flavor components of each ZYN product, their grades, their unique identifiers, and their CAS numbers 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](#). Information on the flavor manufacturers is found in [Section G.3 Product Manufacturing and Controls Summary, Section 1.4](#).

**Table 1 ZYN Finished Product Common Ingredients and Their Intended Function**

Ingredient	Grade	Unique ID	CAS Number	Function
Acesulfame K	Food grade	(b) (4)	(4)	Sweetener
(b) (4)				Processing aid
Hydroxypropyl cellulose	USP			Stabilizer
Maltitol	Food grade			Filler
Microcrystalline cellulose	(b) (4)			Filler
Nicotine bitartrate dihydrate <sup>a</sup>	USP			Other (key ingredient)
Pouch material	USA FDA CFR 21 176.170 & 177.2260			Fiber
Sodium bicarbonate	Food grade			pH adjuster
Sodium carbonate	Food grade			pH adjuster
(b) (4)				Processing aid

Source: Section G.3 Product Manufacturing and Controls Summary, Section 1.4

CAS=Chemical Abstracts Service; EP=European Pharmacopoeia; FCC=Food Chemicals Codex; ID=identification; JP=Japanese Pharmacopoeia; NA=not applicable; NF=National Formulary; USP=United States Pharmacopoeia.

<sup>a</sup> Meets the purity criteria for Nicotine in the USP monograph.

**Table 2 ZYN Finished Product Flavor Components**

ZYN Product Flavor	Unique ID		Flavoring (Unique ID)	Flavor Component	CAS Number
	US	SE			
Cool Mint 3 mg Cool Mint 6 mg	900510 900520	8105 8106	(b) (4)		
Peppermint 3 mg Peppermint 6 mg	901510 901520	8107 8108			
Spearmint 3 mg Spearmint 6 mg	902510 902520	8109 8110			
Wintergreen 3 mg Wintergreen 6 mg	903510 903520	8111 8112			
Citrus 3 mg Citrus 6 mg	907510 907520	8122 8123			
Coffee 3 mg Coffee 6 mg	904510 904520	8124 8125			

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

Source: (b) (4)

CAS=Chemical Abstracts Service; ID=identification; NA=not applicable; SE=Kungals, SE, manufacturing site;  
US=Owensboro, KY, USA, manufacturing site.

### 1.1.1 ZYN Finished Product Component Specifications

#### 1.1.1.1 Nicotine bitartrate dihydrate, (Unique ID (b) (4)) Specification

The nicotine bitartrate dihydrate used in all flavors of ZYN product is produced by (b) (4). While there is no United States Pharmacopeia (USP) monograph for nicotine bitartrate dihydrate, the nicotine bitartrate dihydrate used in the manufacture of ZYN meets the purity criteria of the

USP and European Pharmacopoeia for nicotine. For details of the nicotine bitartrate dihydrate manufacturer and specifications, refer to the (b) (4) Tobacco Products Master File number (b) (4). The Siegfried Ltd letter of authorization is located in [Section A5 TPMF Letters of Authorization](#).

#### 1.1.1.2 Common Ingredients Specifications

The common ingredients used in all flavors of ZYN product are all food-grade or pharmaceutical grade materials that comply with Swedish Match requirements and compendial requirements, where applicable. Certificates of analysis for the common ingredients will be available upon request.

#### 1.1.1.3 Flavor Component Specifications

The flavor compounds used in all flavors of ZYN product are food-grade ingredients and comply with Swedish Match requirements and compendial requirements, where applicable. Certificates of analysis for the flavoring compounds will be available upon request.

#### 1.1.1.4 Pouch Material (Unique ID (b) (4)) Specification

ZYN powder is wrapped in Pouch Material. The pouch paper consists of (b) (4) (b) (4), and (b) (4). The exact composition of the pouch paper is a trade secret of the vendor.

The physical properties of the pouch wrapping material for ZYN products are listed in Table 3.

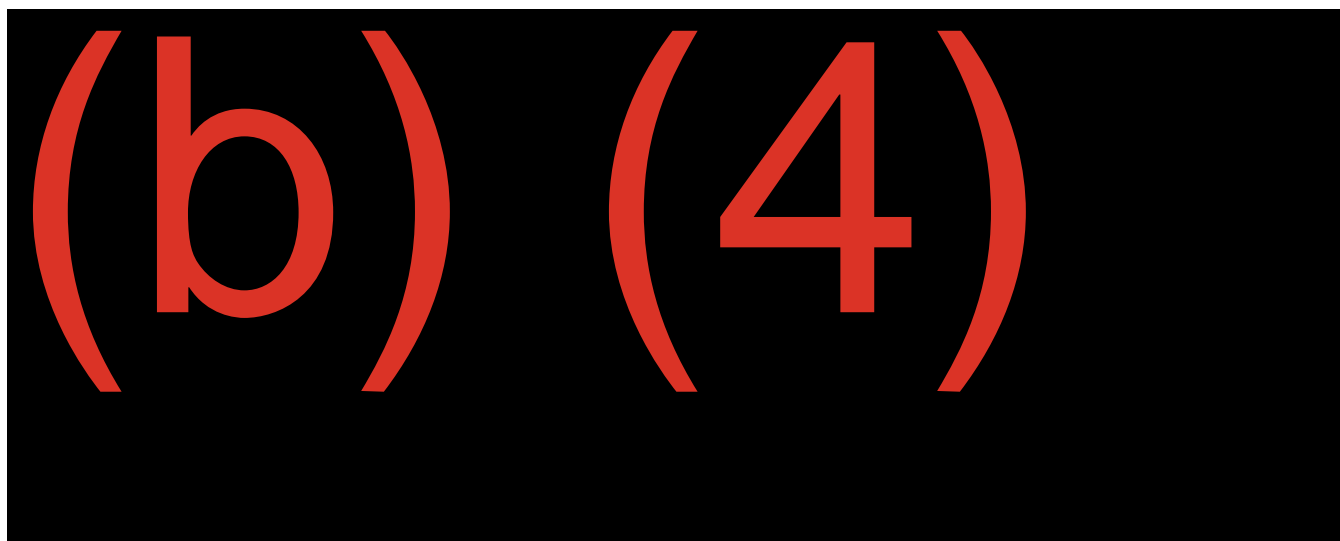
**Table 3 ZYN Pouch Material Parameters**

Parameter	Target	Range
Thickness (mm)	(b) (4)	
Basis weight (g/m2)		
Air permeability (l/m2,sec)		

Source: [Section H.1.2.3.5 Justification of Release Specification and Characterization Testing](#)

A drawing of a filled pouch that is representative of all ZYN flavors and includes targets and tolerances of dimensions is presented in [Figure 1](#).

**Figure 1 ZYN Pouch Drawing**




Source: [Section H.1.2.2 Materials Specifications, Pouch, Drawing](#)

## 1.2 Bulk Container

Between production of ZYN powder and filling the powder into pouches, the bulk powder is held in an intermediate bulk storage container. The bulk storage container is suitable for food products and meets the requirements of 21 Code of Federal Regulations (CFR) 177.1520. For full details of the bulk storage container and closure, refer to [Section H.1.1.2.1 Bulk Container Closure System](#).

The characteristics of the intermediate bulk storage container are listed in Table 4.

**Table 4 ZYN Intermediate Bulk Storage Container (IBC) Characteristics**

Parameter	Owensboro, KY Site	Owensboro, KY Site	Kunglv, SE Site
Manufacturer			
Description			
Function			
Material			
Weight			
Thickness			
Length/Height			
Width			
Volume			

Source: [Section H.1.1.2.1 Bulk Container Closure System](#)

**(b) (4)**

### 1.3 Packaging of ZYN Finished Product

#### 1.3.1 ZYN Finished Product Primary Container (Can and Lid)

After the pouches are filled with powder and sealed, the ZYN finished product is packaged into polypropylene (PP) cans that are closed with a PP lid. Labels are applied to the side and bottom of the can, and to the top of the lid. For details of the finished product pouch filling and packaging operations, refer to [Section G.3 Product Manufacturing and Controls Summary](#), [Section 1.5](#). For details of the can labeling, refer to [Section E.1 Product Packaging and Labeling](#).

##### 1.3.1.1 ZYN Finished Product Primary Container Description

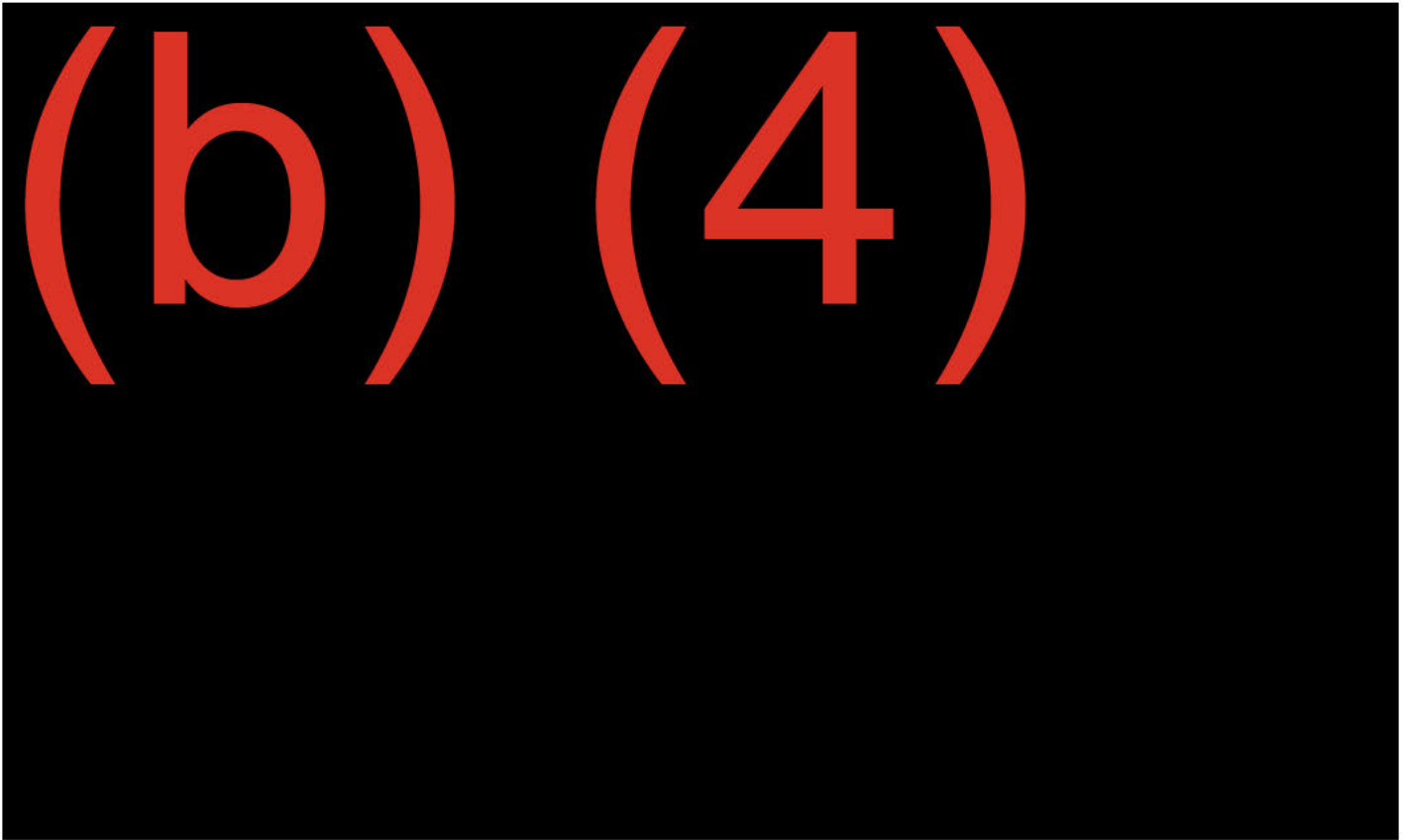
The ZYN finished product primary container and lid dimensions are presented in Table 5. A diagram of the ZYN finished product container/closure is presented in [Figure 2](#). Photos of the ZYN finished product container/closure are provided as [Figure 3](#) and [Figure 4](#).

**Table 5 ZYN Finished Product Primary Container Dimensions**

Parameter	Owensboro, KY Site	Kungaly, SE Site
Manufacturer	(b)	(4)
Can diameter		
Can height		
Can weight		
Lid diameter		
Lid height		
Lid weight		



**Figure 2      ZYN Finished Product Primary Container Drawing**



Source: [Section H.1.1.2.2 Primary Container/Closure System Drawing](#)

**Figure 3      ZYN Finished Product Primary Container Photograph (Empty)**



Source: [Section H.1.1.2.2 Primary Container/Closure System Drawing](#)

**Figure 4 ZYN Finished Product Primary Container Photograph (Filled)**



Source: [Section H.1.1.2.2 Primary Container/Closure System Drawing](#)

#### 1.3.1.2 ZYN Finished Product Primary Container Composition

The ZYN finished product can and lid are manufactured by either (b) (4) or (b) (4). (b) (4) container is manufactured using a PP copolymer supplied by (b) (4) and a colorant supplied by (b) (4). The (b) (4) container is manufactured using a PP resin supplied by (b) (4) and a color masterbatch supplied by (b) (4) ([Section H.1.1.2.2 Primary Closure System Composition](#)). Based on the evaluation of supplier information and compositional statements, it was determined that the PP resins are approved materials for food packaging and are in accordance with 21 CFR 177.1520 for polyolefins. Both the resin and colorants are considered Food and Drug

Administration compliant. For complete details of the colorant and polymer evaluation, for the (b) (4), refer to [Section H.1.1.2.2 Primary Container/Closure Regulatory Compliance Assessment Report](#).

### 1.3.2 ZYN Finished Product Secondary Container (Roll)

#### 1.3.2.1 ZYN Finished Product Secondary Container Composition

The ZYN finished product secondary container consists of five primary containers that are shrink-wrapped in a low-density polyethylene film. A selected representation of the secondary packaging that applies to all finished product stock keeping units is presented in Figure 5.

**Figure 5 ZYN Finished Product Secondary Container**



Source: [Section H.1.1.2.3 Secondary Container Composition](#)

### 1.3.3 ZYN Finished Product Tertiary Container (Case)

#### 1.3.3.1 ZYN Finished Product Tertiary Container Composition

The ZYN finished product tertiary packaging consists of a corrugated cardboard shipping case that holds 18 rolls, equivalent to 90 cans. The cardboard case is assembled with polyvinyl acetate glue and sealed with PP tape. A selected representation of the tertiary packaging that applies to all finished product stock keeping units is presented in [Figure 6](#).



**Figure 6**      **ZYN Finished Product Tertiary Container**



Source: [Section H.1.1.2.4 Tertiary Container Composition](#)