

Zero Tobacco Nicotine Pouches

Section 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

____(Flavor) snus ____ mg/pouch

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses: nicotine pouches for oral

Uses advised against: not determined

1.3 Details of the supplier of the safety data sheet

Company: Porton Pharma Solutions Ltd.

Address: Fangzheng Avenue, Shuitu, Beibei District, Chongqing, China.

Telephone: 023-86083200

E-mail address: porton.db@portonpharma.com

1.4 Emergency telephone number

Telephone: 110(Emergency number), 120(Ambulance), 119 (Fire)

Section 2: Hazards identification

Hazard pictograms
and signal words



Hazard phrases

H301: Toxic if swallowed

H312: Harmful in contact with skin

H315: Causes skin irritation

H318: Causes serious eye damage

H332: Harmful if inhaled.

Safety phrases

P101: If medical advice is needed, have product container or label at hand

P102: Keep out of reach of children.

P264: Wash contacting parts thoroughly after handling.

P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician

P302 + P352: IF ON SKIN: Wash with plenty of soap and water.

P305 + P351+ P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P310: Immediately call a POISON CENTER or doctor/physician.

P501: Dispose of contents/container to designated place in accordance with local/regional/national/international regulations.

Names of components on the label

Contains: Benzoic acid

2.3 Other hazards:

Product does not contain ingredients, which meet criteria for PBT or vPvB accordance with Annex XIII of REACH Regulation.

Section 3: Composition/information on ingredients

3.1 Substance: Not applicable. Please refer to 3.2 for more information

3.2 Mixtures:

Ingredient Name	CAS No.	%By Weight (% Active)
Microcrystalline cellulose	9004-34-6	50

Mannitol	69-65-8	10
Acesulfame	55589-62-3	2
Sodium Carbonate	497-19-8	3
Glycerol	56-81-5	5
Propanediol	57-55-6	5
Natrium Bicarbonate	144-55-8	3
Medium chain triglycerides	73398-61-5	2
Xylitol	87-99-0	10
Povidone	9003-39-8	5

Additional information:

Substances for which there are Union workplace exposure limits are listed in SECTION 8 For full text of H-statements: see SECTION 16.

Section 4: First aid measures

4.1 Description of first aid measures

Skin contact: take off contaminated clothing. Wash the contaminated skin with water and soap. Immediately consult a doctor.

Eye contact: remove contact lenses. Wash the contaminated eye with plenty of water for at least 15 minutes. Avoid powerful water stream. Consult a doctor if disturbing symptoms occur.

Ingestion: do not induce vomiting. Rinse mouth with water. Never give anything to drink to an unconscious person. Consult a doctor. Show the container or label.

Inhalation: Remove to fresh air. Keep warm and calm. Consult a doctor, if disturbing symptoms appear.

4.2 Most important symptoms and effects, both acute and delayed:

None reasonably foreseeable

4.3 Indication of any immediate medical attention and special treatment needed:

Physician makes a decision regarding further medical treatment after thoroughly examination of the injured. Symptomatic treatment.

Section 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Foam, dry extinguishing agents, water spray

Unsuitable extinguishing media: Water jet - risk of the propagation of the flame

5.2 Special hazards arising from the substance or mixture:

During the fire, the product may produce toxic fumes of carbon monoxide and dioxide, nitric oxides and other unidentified products of thermal decomposition. Do not inhale combustion products.

5.3 Advice for firefighters:

Personal protection typical in case of fire. Do not stay in the fire zone without self-contained breathing apparatus and protective clothing resistant to chemicals.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Limit the access for the outsiders into the breakdown area, until suitable cleaning operations are completed. In case of large spills, isolate the exposed area. Avoid contact with skin and eyes. Use personal protective measures.

6.2 Environmental precautions:

In case of release of large amounts of the product, it is necessary to take appropriate steps to prevent it from spreading into the environment. Material may be hazardous if released in large quantities to the environment. Notify relevant emergency services.

6.3 Methods and material for containment and cleaning up

Damaged container put in emergency container. Absorb leakage with incombustible liquid-binding material (e.g. Sand, earth, universal binders, silica, vermiculite) and collect

mechanically into properly labeled containers for disposal. Clean the contaminated place.

6.4 Reference to other sections: Section 13 and section 8

Section 7: Handling and storage

7.1 Precautions for safe handling:

Handle in accordance with good occupational hygiene and safety practices. Avoid skin and eyes contamination. Before break and after work wash hands carefully. Use personal protective measures. Ensure adequate ventilation. Do not let the product to get into mouth.

7.2 Conditions for safe storage, including any incompatibilities:

Keep only in original, tightly closed containers in a cool and well-ventilated area. Keep away from food, beverages or feed for animals. Avoid direct exposure to sunlight. Keep away from strong acids and oxidizing agents. After opening, seal the container and store in an upright position to prevent leakage.

Section 8: Exposure controls/personal protection

8.1 Control parameters

Substance	Country	OEL value
Nicotine	Work evaluating existing limits, Germany, Denmark, France, Norway, Belgium, Spain, Ireland	0.5mg/m ³ (8h)
	Finland, United Kingdom	0.5mg/m ³ (8h) 1.5mg/m ³ (15min)
	Austria, Switzerland	0.5mg/m ³ (8h)

		1.5mg/m ³ (15min)
	Sweden	0.1mg/m ³ (8h)
Propanediol	REACH Regulations	10 mg/m ³ Inhalation, local effects Long-term exposure 168 mg/m ³ Inhalation, systemic effects Long-term exposure
	United Kingdom	474 mg/m ³ (8h)
	Norway	79 mg/m ³ (8h)
	Ireland	470 mg/m ³ (8h)-Vapor and particulates 10 mg/m ³ (8h)-Particulates

Legal Basis: Commission Directive 2006/15/EC, 200/39/EC, 2009/1061/EC

Recommended control procedures

Procedures Concerning the control over the dangerous components concentration the air and control over the air a quality in the workplace in Accordance with the European Standards.

8.2 Exposure controls:

Use the product in accordance with good occupational hygiene and safety practices. Ensure exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below irrespective threshold limit value. Ensure eye stations and safety showers.

Hand and body protection:

In case of short term contact use protective gloves made of nitrile rubber (minimal thickness: 0.2 mm; breakthrough time > 30 minutes). In case of long term contact use protective gloves made of butyl rubber (minimal thickness: 0.3 mm, breakthrough time > 480 minutes).

The material that the gloves are made of must be impenetrable and resistant the product's effects. The selection of material must be performed with consideration of breakthrough time, penetrant speed and degradation.

Eye protection:

Wear tightly fitting safety glasses if there is a risk of eye contamination

Respiratory protection:

In case of normal use, in accordance with the intended use, it is not necessary.

Applied personal protective equipment must comply with the requirements of Directive 89/686/EC. The employer

is obliged to provide protective equipment relevant to performed activities and in accordance with all quality requirements, including its maintenance and cleaning.

8.3 Environmental exposure controls:

Do not allow large amounts of product to reach ground water, sewage, waste water or soil.

Section 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: Yellow oily liquid at room temperature

Odour: Not available

Odour threshold: Not available

pH: Not available

Melting point/freezing range: Not available

Initial boiling point and boiling range: Not available

Flash point: Not available

Evaporation rate: Not available

Flammability (solid, gaseous): This product is liquid, not available.

Upper/lower flammability or explosive limits: Not available

Vapour pressure: Not available

Vapour density: Not available

Relative density (water=1g/mL): Not available

Solubility(ies): Not available

Partition coefficient: n-octanol/water: Not available

Auto-ignition temperature: Product is not self-igniting.

Decomposition temperature: Not available

Viscosity: Not available

Explosive properties: Product does not present an explosion hazard.

Oxidizing properties: Product does not present oxidizing properties

9.2 Other information: Not available

Section 10: Stability and reactivity

10.1 Reactivity: Product is feebly reactive. Product does not undergo a dangerous polymerization. See also 10.4-10.5

10.2 Chemical stability: The product is stable under normal storage and using condition

10.3 Possibility of hazardous reactions: Dangerous reactions are not known.

10.4 Conditions to avoid: Avoid direct exposure to sunlight.

10.5 Incompatible materials: Strong oxidizing agents, acids.

10.6 Hazardous decomposition products: Not available

Section 11: Toxicological information

11.1 Information on toxicological effects

Toxicity of components

LD/LC50 values relevant for classification		
CAS: 54-11-5 Nicotine		
Oral	LD50	5mg/kg bw
Dermal	LD50	70mg/kg bw
Inhalation	LC50	0.19 mg/L(dusts/mists)

Toxicity of the mixture

The acute toxicity estimate (ATE_{mix}) for the classification of a substance in a mixture was determined using the appropriate value from ECHA website.

Acute toxicity

ATEmix (oral)=277.8mg/kg bw (Acute Tox. 3 (H301))

ATEmix (dermal) = 3889.2 mg/kg bw (Not classified)

ATEmix (inhalation) = 10.6 mg/L (Not classified)

Skin corrosion/irritation:

Based on available data, this product can cause skin irritation.

Serious eye damage/irritation:

Based on available data, this product can cause skin sensitization.

Respiratory or skin sensitization:

Based on available data, the classification criteria are not met.

Germ cell mutagenicity:

Based on available data, the classification criteria are not met.

Carcinogenicity:

Based on available data, the classification criteria are not met.

Reproductive toxicity:

Based on available data, the classification criteria are not met.

Summary of evaluation of the CMR properties:

Based on available data, the classification criteria are not met.

STOT-single exposure:

Based on available data, the classification criteria are not met.

STOT-repeated exposure:

Based on available data, the classification criteria are not met.

Aspiration hazard:

Based on available data, the classification criteria are not met.

Section12:Ecological information

12.1 Toxicity:

Parameters of environmental toxicity
CAS:54-11-5 Nicotine

Classification:	Aquatic Chronic 2(H411)
Fish(Oncorhynchus mykiss) Fish(fresh water) Daphnia(Daphnia magna) Alga(Desmosomes substitutes)	LC50-96H=4mg/L 3-29 ppm EC50-48h=0.24mg/L EC50-72h=37mg/L

According to Regulation (EC) No 1272/2008, this product does not meet the criteria of classification of environmental toxicity.

12.2 Persistence and degradability:

Data for the mixture are not available.

Nicotine	
OECD Guideline 301B	71% degradation after 28 days
Propanediol	
OECD Guideline 301F Biodegradation in soil Photo transformation in water	81% biodegradation High concentrations of propylene glycol released into a soil environment can be expected to biodegrade Readily biodegradable

12.3 bioaccumulative potential:

Data for the mixture are not available.

Nicotine	
Log Po/w	-1.75(pH=7.4,25°C)
Propanediol	
BCF	0.09

12.4 Mobility in soil:

Data for the mixture are not available.

Propanediol	
Koc	Koc
Henry's Law constant	Henry's Law constant

12.5 Results of PBT and vPvB assessment:

Product does not contain ingredients, which meet criteria for PE3T or vPvB

12.6 Other adverse effects:

The mixture is not classified as hazardous to the ozone layer.

Section13:Disposal considerations

13.1 Waste treatment methods

Disposal method for the product: disposal in accordance with the local legislation. Do not empty into drains. Waste code should be given in the place of waste formation. The classification of this waste meets criteria for dangerous waste. Disposal methods for used packing: reuse/recycling/liquidation of empty containers dispose in accordance with the local legislation. The classification of this waste meets criteria for dangerous waste.

Legal Basis: Directive 2008/98/EC, 94/62/EC.

Section14: Transport information

14.1. UN number:

ADR: UN 3144

IMDG: UN 3144

ICAO: UN 3144

14.2. UN proper shipping name:

ADR: ____ (Flavor) snus ____ mg/pouch

IMDG: ____ (Flavor) snus ____ mg/pouch

ICAO: ____ (Flavor) snus ____ mg/pouch

14.3. Transport hazard class(es):

ADR: Class 6.1: Toxic substances

IMDG class: Class 6.1: Toxic substances

ICAO class: Class 6.1: Toxic substances

Transport pictograms on the label:



14.4. Packing group:

ADR: III

IMDG: III

ICAO: III

14.5. Environmental hazards:

Not available

14.6. Special precautions for user:

Move carefully to prevent leakage during carriage. Keep necessary protective articles at hand in case of accident.

Use emergency escape mask when in need.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code":

Not available

Section 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the

Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals

Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission

Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC,

93/67/EEC, 93/105/EC and 2000/21/EC.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification,

labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC,

and amending Regulation (EC) No 1907/2006 (Text with EEA relevance)

Commission Regulation (EU) No 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the

European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals

(REACH) (Text with EEA relevance)

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing

certain Directives.

European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste.

Economic commission for Europe Committee on Inland Transport ECE/TRANS/257(Vol. I) of applicable as from 1 January 2017 European Agreement concerning the International Carriage of Dangerous (ADR)

Convention concerning International Carriage by Rail (COTIF): Appendix C - Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) with effect from 1 January 2017.

Technical Instructions for the Safe Transport of Dangerous Goods by Air: Order Number: Doc 9284, 2017-2018 Edition.

15.2 Chemical safety assessment:

A Chemical Safety Assessment is not required for mixtures in accordance with REACH

Regulation.

Section 16: Other information

Full text if indicated H phrases mentioned in section 2,3:

H300: Fatal if swallowed

H301: Toxic if swallowed

H302: Harmful if swallowed

H310: Fatal in contact with skin

H330: Fatal if inhaled

H411: Toxic to aquatic life with long lasting effects

Clarifications of aberrations and acronyms

Acute Tox. 2, 4: Acute toxicity, Category 2, 4

Aquatic Chronic 2: Hazardous to the aquatic environment, long-term hazard Category 2

Eye Dam. 1: Serious eye damage, Category 1

Skin Irrit. 2: Skin irritation, Category 2

PBT: Persistent, Bioaccumulate and Toxic substance

vPvB: very Persistent, very bioaccumulate substance

OECD: Organization for Economic Co-operation and Development

OEL value: Occupational exposure limit value

LC50: Median Lethal concentration

LD50: Median Lethal dose

ATE mix: Acute Toxicity Estimate of mixture

bw: body weight

LoW: List of Wastes

Trainings:

Before commencing working with the product, the user should learn the Health & Safety regulations, regarding

handling chemicals, and in particular, undergo a proper workplace training

Key literature references and sources for data:

This SDS was prepared on the basis of sheets of the individual components, literature data, online databases (eg. ECHA)

as well as our knowledge and experience, taking into account current legislation.

Methods of evaluating information which was used for the purpose of classification acc.

Regulation (EC) No 1272/2008

Acute Tox. 3 (H301): calculation method

Methods of evaluating information which was used for the purpose of transport acc.

ECE/TRANS/242 (Vol.I): Not applicable

Other data

Purity of the ingredients present in Section 3 is > 98%, and does not affected classification

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Composed by: CAI (on the basis of Central in China data)

THIS SDS ANNULS AND REPLEACES ALL PREVIOUS VERSIONS

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