

**Evaluation of  
Honey  
For Use as an Ingredient in  
Tobacco Products**

April 2009

## **INTRODUCTION**

Honey (CAS # 8028-66-8) is currently used worldwide at levels up to **37'000 ppm** in selected brands of tobacco products manufactured and/or distributed by Philip Morris International, including cigarettes and fine-cut tobacco. This document is a review of the published toxicology information on honey abstracted from online toxicity databases.

### ***Overview<sup>a</sup>***

The following information was generated from the MICROMEDEX database system <http://csi.micromedex.com> on April 29<sup>th</sup> 2009, unless otherwise indicated.

Honey is the natural substance produced by honey bees from the nectar of plants or from secretions of living parts of plants or excretions of plant sucking insects on the living parts of plants, which the bees collect, transform by combining with specific substances of their own, deposit, dehydrate, store and leave in the honey comb to ripen and mature<sup>[1]</sup>. Honey is regarded as food and has been used since ancient times. The Greeks and Romans were the first to recognize honey as a valuable food commodity. Since prehistoric times, the use of honey as a food has continued to grow, resulting in worldwide use in many food products. Although honey can be consumed directly from the sealed combs, most of the honey consumed today undergoes at least some sort of minimal processing.

As a food flavouring additive, the material has been assessed under the provisions of the *Federal Food, Drug and Cosmetic Act, section 201 (s)*, to be generally recognised as safe (GRAS) under current conditions of use. The European standard classifies honey according to origin of blossom and by processing mode.

The use of honey on tobacco products is regulated in several countries worldwide. It is approved for use in tobacco products as an additive or flavouring in several countries with tobacco product regulations, including *e.g.*, Belgium, Croatia, Czech Republic, Egypt, Finland, France, Germany, Great Britain, Hungary, Lithuania, Macedonia, Romania, Slovak Republic, Spain and Switzerland. Apart from countries that approve its use, there is no country, regardless of the extent to which tobacco products are regulated therein, that affirmatively prohibits the use of this ingredient on tobacco products.

## **TOXICITY DATA ON UNBURNT MATERIAL**

As honey is food and is generally regarded as safe (GRAS) no short term or long term toxicity studies, including genotoxicity or mutagenicity of honey, were found in the literature. However, Scott *et al.* (1971)<sup>[2]</sup> studied the LD<sub>50</sub> of honey because of its contents of grayanotoxins. The LD<sub>50</sub> of honey, collected from the Grouse Mountain areas of Turkey, in

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<sup>a</sup> **Note:** Philip Morris International shares the concerns of regulators and the public health community about the proliferation of certain cigarette brands that have a predominantly candy-like or fruity flavour and are particularly appealing to minors, and we support legislation that would ban such cigarettes. However, there is currently no consistent terminology used by regulators and the public health community to describe such cigarettes. This can lead to confusion and potential for misinterpretation. In this document, any references to flavours or "smoke aroma" or flavour perceptions such as "sweet", "fruity", etc. are not meant to describe a flavour, taste or aroma that would dominate the taste of the final product, let alone dominate it in a way that is appealing to minors. Rather, such references are only used to explain the differences and nuances between the various flavours described in this and related documents.

mouse was 34 g/kg (95 % confidence limits 17.5-65 g/kg). Symptoms in mice were similar to those observed with the toxic grayanotoxins. In mouse studies, grayanotoxins I and II had effects similar to those of toxic honey, with LD<sub>50</sub> values of 1.28 and 0.91 mg/kg, respectively. Grayanotoxin II was not toxic up to 4 mg/kg<sup>[2]</sup>. Kandil *et al.*<sup>[3]</sup> reported pretreatment of rats with 0.5 g honey for 7 days raised the LD<sub>50</sub> of digoxin 15%. Onat *et al.*<sup>[4]</sup> studied the toxicity of grayanotoxins in rats and found bradycardia and respiratory rate depression. Atropine (2 mg/kg) treatment improved both bradycardia and respiratory rate depression<sup>[5,6]</sup>. Grayanotoxins isolated from honey from Black Sea Region of Turkey increased the threshold velocity and decreased conduction velocity of isolated frog sciatic muscle<sup>[6,7,8]</sup>.

## **TOXICITY DATA ON BURNT MATERIAL**

Data on the toxicity of honey as a cigarette ingredient has been evaluated in a series of studies. The results of these studies may be found in the following references:

Baker R.R. *et al.* 2004, "An overview of the effects of tobacco ingredients on smoke chemistry and toxicity", Food and Chemical Toxicology, 42S:53-83. \*\*PEER REVIEWED\*\*

Gaworski C.L. *et al.* 1999, "Toxicological evaluation of flavor ingredients added to cigarette tobacco: skin painting bioassay of cigarette smoke condensate in SENCAR mice," Toxicology, 139 1-17. \*\*PEER REVIEWED\*\*

## **CONCLUSION**

Smoking causes lung cancer, heart disease, emphysema and other serious diseases in smokers. Smokers are far more likely to develop serious diseases, like lung cancer, than non-smokers. There is no "safe" cigarette. Government health warnings about smoking apply to all cigarettes, regardless of the ingredients added, including those containing only tobacco and paper.

While Philip Morris International has not conducted human studies on the health effects of ingredients used in cigarette manufacture, studies have been conducted by Philip Morris International and/or others using scientifically accepted *in vitro* and *in vivo* toxicity assays with various ingredient mixtures. These studies show there is no meaningful difference in the composition or toxicity of smoke when the smoke from cigarettes with the added ingredient is compared to the smoke from cigarettes without this added ingredient. Based on a review of current published toxicological information, it is our scientific judgement that the addition of honey as an ingredient, at the levels used in our brands, does not increase the overall toxicity of tobacco smoke.

## References

1. Codex Alimentarius Commission *Codex Standard for Honey*. CODEX STAN 12-1981 (1981).
2. Scott, P. M., Coldwell, B. B. & Wiberg, G. S. *Grayanotoxins. Occurrence and analysis in honey and a comparison of toxicities in mice*. Food Cosmet Toxicol 9, 179-184. 1971.
3. Kandil, A., El-Banby, M. A. & Gamil, W. M. *Protective properties of floral and non-floral honeys against digoxin overdose toxicity*. Journal of Drug Research (Egypt) 17, 247-252. 1987.
4. Onat, F., Yegen, B. C., Lawrence, R. & Oktay, A. O. S. *Site of action of grayanotoxins in mad honey in rats*. J Appl Toxicol (11), 199-201. 1991.
5. Onat, F. Y., Yegen, B. C., Lawrence, R. & Oktay, A. O. S. *Mad honey poisoning in man and rat*. Rev Environ Health 9, 3-9. 1991.
6. Onat, F., Kurtel, H., Yegen, B. C., Oktay, A. & Oktay, S. *Atropine and AF-DX 116 in mad honey intoxication*. European . Journal of Pharmacology 183, 575. 1990.
7. Ozesmi, C., Aydogan, S. & Ascioğlu, M. *Effects of honey containing grayanotoxin I on frog gastrocnemius muscle*. Vet.Hum Toxicol 36, 117-119. 1994.
8. Ascioğlu, M. & Ozesmi, C. *Effects of grayanotoxin-I on threshold intensity and compound action potential of frog sciatic nerve*. J Physiol Pharmacol 47(341), 349. 1996.

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## Safety Data Sheet

According to Regulation ST/SG/AC.10/30/Rev.2 UN GHS

This Safety Data Sheet cancels and replaces all preceding SDS for this product.

### 1 IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

**862255 TP0299**  
HONEY FLAVOR  
© Firmenich product

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

Concentrated aromatic raw material.  
Not for personal use in this form or concentration.  
For manufacturing use only.

#### 1.3 Details of the supplier of the safety data sheet

**Dr. Daniel Grell**  
Firmenich SA  
Case postale 239  
CH - 1211 GENEVE 8  
daniel.grell@firmenich.com  
Tel: +41.22/780.22.11 - Fax: +41.22/343.73.22

#### 1.4 Emergency telephone number

Tel:+41.22.780.37.90  
Available 24/7 (NCEC)

### 2 HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance or mixture

##### 2.1.1 Classification according to Regulation ST/SG/AC.10/30/Rev.2 [UN/GHS]

Not Classified according to the rules of the UN GHS.

##### 2.1.2 Classification according to 67/548/EEC or 1999/45/EC

Not classified according to Council Directives 67/548/EEC and 1999/45/EC as amended.

##### 2.1.3 Additional information

Full text of R- and S-phrases: see section 16

#### 2.2 Label elements

Not Classified according to the rules of the UN GHS.

#### 2.3 Other hazards

No data available at this time.

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### **3 COMPOSITION/INFORMATION ON INGREDIENTS**

Mixture of aromatic substances.

### **4 FIRST-AID MEASURES**

#### 4.1 Description of first aid measures

General information:

As in all cases of potential poisoning, Obtain medical advice immediately.

In case of eye contact:

Irrigate copiously with water for at least 10 minutes. Obtain medical advice if any irritation or evidence of tissue damage persists.

In case of inhalation:

Remove the individual to fresh air and keep at rest. Obtain medical advice immediately.

In case of skin contact:

Remove contaminated clothes. Wash skin with large volumes of water.

If irritation persists, or any sign of tissue damage is apparent, obtain medical advice immediately.

In case of ingestion:

Rinse mouth with water. Obtain medical advice immediately.

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

#### 4.3 Indication of immediate medical attention and special treatment needed

### **5 FIRE-FIGHTING MEASURES**

#### 5.1 Extinguishing media

In the event of fire, adequate extinguishers should be used. Avoid inhalation of smoke and fumes. In case of insufficient ventilation, wear suitable respiratory equipment.

#### 5.2 Special hazard arising from the substance or mixture

No specific hazard known.

#### 5.3 Advice for fire-fighters

No specific advice.

### **6 ACCIDENTAL RELEASE MEASURES**

#### 6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:

Adequate protective gloves should be worn when handling spillages. No smoking. Avoid naked flames or other potential sources of ignition (eg. electrical equipment).

Avoid skin contamination and inhalation of dust.

Individual washing routines should be followed after any potential contact.

Ensure adequate ventilation in working areas following accidental releases.

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For emergency personnel:  
Apply the same recommendations as section 6.1

### 6.2 Environmental precautions

Do not discharge directly into drains, air, into soil or into the aquatic environment.

### 6.3 Methods and material for containment and cleaning up

For containment:

For cleaning-up:  
Spillages should be disposed of in accordance with Governmental Regulations.

## **7 HANDLING AND STORAGE**

### 7.1 Precautions for safe handling

Keep strict control of dust accumulation to a minimum.  
Avoid contact with skin and eyes.  
Wear adequate protective gloves protection and eye/face protection.  
No smoking. Avoid any source of ignition. Use flameproof electrical equipment and spark-reduced tools.  
Ensure that all equipments are properly bonding and earthing.  
Avoid exposing to high temperature during processing.  
Do not ingest or apply to the skin as such. Good personal washing routines should be followed.  
Maintain adequate local and general ventilation where product is handled.

#### 7.1.1 Protective measures

Keep strict control of dust accumulation to a minimum. Maintain adequate local and general ventilation where product is handled. Avoid any sources of ignition.

#### 7.1.2 Advice on general occupational hygiene

Good personal washing routines should be followed.

### 7.2 Conditions for safe storage, including any incompatibilities

It is good general practice to store in closed, preferably full, containers away from heat sources, and protected from extremes of temperature. Do not re-use the empty container.  
Respect general rules for compatibility storage.

### 7.3 Specific end use(s)

Not available at this time.

## **8 EXPOSURE CONTROLS/PERSONAL PROTECTION**

### 8.1 Control parameters

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### 8.2 Exposure controls

Avoid exposing to high temperature during processing.  
Maintain adequate local and general ventilation where product is handled.

#### 8.2.1 Appropriate engineering controls

Maintain adequate local and general ventilation where product is handled and dispensed.

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### 8.2.2 Environmental exposure controls

Not available at this time. Minimize release to the environment.

### 8.3 Personal protection

Respiratory protection: Use adequate self respiratory apparatus.

Hand protection: Adequate Protective Gloves should be worn.

Eye protection: Adequate safety glasses should be used.

Skin protection: Wear protective clothing, overall if necessary to limit the odour contamination of personal clothing. Individual washing routines should be followed after any potential contact.

## 9 PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance : POWDER  
Colour : WHITE TO BEIGE  
Odour : Characteristic strong odour according to the commercial description of the substance.

pH : Not applicable  
Melting point/range (°C) : Not available  
Initial boiling point/range (°C) : Not available  
Flash point (closed cup) : > 100°C  
Evaporation rate : Not available  
Flammability (solid/gas) : Not available  
Upper/lower flammability or explosive 1 limits :  
Vapour pressure (Pa) : Not applicable  
Vapour density : Not available  
Relative density (d 20/20) : Not available  
Water solubility (20°C) : Not applicable  
Partition coef. (n-octanol/water) : Not applicable  
Auto-ignition temperature : Not available  
Decomposition temperature : Not available  
Viscosity : Not available  
Oxidizing properties : Not available

### 9.2 Other safety information

#### 9.2.1 Explosive properties (Measured)

- St 1 -

#### 9.2.2 Default Safety Data for Spray Dryer Dust Compounds

Using our experience in Powder operations and internal "Safety Dust Data Base Results", we established the following "Default Parameters Profile". These "Default Parameters" should never be used for production, storage, transportation or any other industrial purpose.

On all cases, if specific data are needed, the physical measurement is the best way to get data of our compounds.

Type	Value	Units
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- Particle size distribution	> 10	microns
- Moisture content	< 8	%
- Minimum explosible concentration	> 15	g/m <sup>3</sup>
- Minimum ignition energy of cloud (MIE)	> 1	mJ
- Minimum ignition energy in layer (MIE)	> 1	mJ
- Cloud ignition temperature [1]	> 100	°C
- Layer ignition temperature (5 mm layer according to the applicable norm) [2]	MELT	°C
- KST	< 400	bars.m/s
- Pmax (abs)	< 11	Bars
- St	3	-
- Resistivity	> 1.E10	Ohm.m

[1] The minimum ignition temperature of a dust cloud is the lowest temperature at which a surface in contact with an explosive mixture of combustible dust and air can ignite the mixture. The temperature for this powder is not below 120°C and we have to heat up to around 200-300°C or more for possible gases decomposition ignition.

[2] The smoldering /glow temperature can only be determined for substances that do not decompose, melt or evaporate before smoldering. In this case the MSDS mentioned "MELT". This powder melt around 120-130°C already before burning.

## **10 STABILITY AND REACTIVITY**

### 10.1 Reactivity

No reaction known with water.

### 10.2 Chemical stability

Good stability at standard temperature.

### 10.3 Possibility of hazardous reactions

Not known.

### 10.4 Conditions to avoid

Avoid temperatures above or at least 5 °C below flash point for any flammable liquids.

Do not heat closed containers.

Avoid contact with oxidizing agents.

### 10.5 Incompatible materials

Not known.

### 10.6 Hazardous decomposition products

Contact with water or storage under recommended conditions for one year should not produce dangerous decomposition products.

## **11 TOXICOLOGICAL INFORMATION**

This preparation has not been subjected to toxicological testing as an entity but has been blended from materials with established toxicological bibliographies. In view of the difficulty of using current standard toxicological evaluation techniques to predict potential hazards to susceptible individuals or arising from unforeseeable potentiation, this preparation should be considered and handled as if it displayed health hazards and treated in consequence with all possible precaution.

## **12 ECOLOGICAL INFORMATION**

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This preparation has not been subjected to ecotoxicological testing as an entity. In view of the difficulty of using current standard ecotoxicological evaluation techniques to predict the impact of particular modes of release on vulnerable or localised parts of the ecosystem, this preparation should be considered and handled as if it displayed potential environmental hazards, and treated in consequence with all possible precaution.

### **13 DISPOSAL CONSIDERATIONS**

Residual quantities of the product should be treated according to the instructions given under points 6, 7 and 8 above. Wastes should be eliminated according to national or regional regulatory requirements currently in force.

Minimize release to the environment.

### **14 TRANSPORT INFORMATION**

In case of accidental spillage or fire during transport, refer to instructions given under points 5, 6, 7 and 8 above.

#### 14.1 UNO

UN-No:	Not regulated
Proper Shipping Name:	N/A
Class:	----
Packing Group:	---

#### 14.2 Land transport (ADR/RID)

UN-No:	Not regulated
Proper Shipping Name:	N/A
Class:	----
Packing group:	---

#### 14.3 Sea transport (IMDG-Code)

UN-No:	Not regulated
Proper Shipping Name:	N/A
Class:	----
Packing group:	---

#### 14.4 Air transport (ICAO-IATA)

UN-No:	Not regulated
Proper Shipping Name:	N/A
Class:	----
Packing group:	---

### **15 REGULATORY INFORMATION**

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

No relevant information available at this time.

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### 15.2 Chemical Safety Assessment

No data available at this time.

## **16 OTHER INFORMATION**

### 16.1 Revisions

01-Dec-2010: Version 1.1 - First version validated for publication

### 16.2 Key literature references

RIFM database  
OECD SIDS  
EU IUCLID  
Supplier information

**We believe that the information contained herein is current as of the date of this Safety Data Sheet. Since the use of this information and the conditions of use of the product are not within the control of Firmenich, it is the user's obligation to determine conditions of safe use of the product.**

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