

CONFIDENTIAL – 12 July 2019



## **Diacetyl, ingredient added to cigarettes Literature review A preliminary scientific summary**

### **HIGHLY CONFIDENTIAL KTI:**

Maximum use value of the ingredient in tobacco blend:

- 0,00039 mg meaning 0,4 µg/cigarette
- expressed on a wet weight basis: 0,00005% by percentage or 0,5 ppm
- expressed on a dry weight basis: 0,000058% by percentage or 0,58 ppm.

### **Summary**

Diacetyl<sup>1</sup> (or 2,3-butanedione) is diketone registered as CAS 431-03-8, CoE 752, FEMA 2370, generally recognize as safe; it is a natural and artificial flavor providing a butter-like aroma.

Pyrolysis study<sup>2</sup> referring to the burning of the tobacco rod showed that diacetyl remains intact and transfers to mainstream smoke.

Diacetyl is a natural constituent<sup>3 4, 5, 6</sup> of tobacco and tobacco smoke.

- Level of the added ingredient in the tobacco blend is very low compare to natural levels of diacetyl.
- Tobacco natural flavor includes the butter-like diacetyl flavor, and therefore diacetyl cannot be seen as a characterizing flavor.

Published data of Diacetyl smoke emission showed:

- the order of magnitude of the range of smoke emissions<sup>7, 8</sup> within different smoking regimes - from tens to hundreds of micrograms per cigarette - a high variability even on an unflavored reference product was observed.
- some confusing data<sup>9</sup> due to the unrealistic protocol applied for the measurement, nevertheless such unrealistic values were considered for risk assessment and by consequence provide misleading conclusion for this risk assessment
- no increase of measurable level of diacetyl in smoke emissions between flavored and unflavored tobacco products were observed<sup>8</sup>.

Diacetyl was usually part of the series of publications assessing the effect of additives in tobacco blends, these studies<sup>10, 11, 12, 13, 14, 15, 16, 17, 18, 19</sup> provide a key source of information showing that addition of this ingredient showing no measurable health effect.

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Taking into account the very small amount of the ingredient compared to the natural levels in tobacco and/or smoke, it cannot raise any question regarding attractiveness and addictiveness.

Diacetyl is present in a wide range of food products and its health effect at the occurring levels is questionable and not clearly established<sup>8, 20, 21, 22</sup>

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SYNAPCION  
B. TEILLET



## REFERENCES

- <sup>1</sup> G. A. Burdock, Fenaroli's handbook of flavor ingredients, fourth edition, CRC Press (2002) 401-402
- <sup>2</sup> R. R. Baker, The pyrolysis of tobacco ingredients, J. Anal. Appl. Pyrolysis (2004) 71:223-311
- <sup>3</sup> A. Rodgman, T. A. Perfetti, the chemical components of tobacco and tobacco smoke, CRC Press (2009) 254
- <sup>4</sup> Tobacco and Tobacco Smoke, E.L. Wynder and D. Hoffmann, Carbonyl contents of tobacco, Academic Press Inc. (1967) 408
- <sup>5</sup> C. Leffingwell et Al., Volatile constituents of perique tobacco, Electronic J. Environ. Agric. Food Chem. (2005) 4:899-915
- <sup>6</sup> A. Rodgman et Al., The chemical component identified in tobacco and tobacco smoke prior to 1954: A chronology of classical chemistry, Beitr. Tabakforsch. Int. (2009) 23:277-333
- <sup>7</sup> G.M. Polzin et Al., Analysis of volatile organic compounds in mainstream cigarette smoke., Environ. Sci. Technol. (2007) 41:1297-1302
- <sup>8</sup> S. Pierce et Al., Diacetyl and 2,3-pentanedione exposures associated with cigarette smoking: implications for risk assessment of food and flavoring workers, Crit Rev Toxicolo. (2014) 44(5):420-435
- <sup>9</sup> K. Fujoka et Al., Determination of toxic carbonyl compounds in cigarette smoke, Environ Toxicol (2006) 21:47-54
- <sup>10</sup> C.L. Gaworski et Al., Toxicologic evaluation of flavor ingredients added to cigarette tobacco: 13-week inhalation exposures in rats, Inhalation Toxicology (1998) 10:357-381
- <sup>11</sup> P.M. Vanscheeuwijck et Al., Evaluation of the potential effects of ingredients added to cigarettes. Part 4: subchronic inhalation toxicity, Food and Chemical Toxicology (2002) 40:113-131
- <sup>12</sup> E. Roemer et Al., Evaluation of the potential effects of ingredients added to cigarettes. Part 3: in vitro genotoxicity and cytotoxicity, Food and Chemical Toxicology (2002) 40:105-111
- <sup>13</sup> K. Rustermeier et Al., Evaluation of the potential effects of ingredients added to cigarettes. Part 2: chemical composition of mainstream smoke, Food and Chemical Toxicology (2002) 40:93-104
- <sup>14</sup> E. L. Carmines, Evaluation of the potential effects of ingredients added to cigarettes. Part 1: cigarette design, testing approach, and review of results, Food and Chemical Toxicology (2002) 40:77-91
- <sup>15</sup> T. Paschke et Al., Effects of ingredients on cigarette smoke composition and biological activity: a literature review, Beitr. Tabakforsch. Int. (2002) 20:107-247
- <sup>16</sup> R. R. Baker et Al., Toxicological aspects of tobacco flavor ingredients, Recent Advances in Tobacco Science (2003) 29:1-37
- <sup>17</sup> R. R. Baker et Al., An overview of the effects of tobacco ingredients on smoke chemistry and toxicity, Food and Chemical Toxicology (2004) 42S: S53-S83
- <sup>18</sup> R. Baker et Al., The effect of tobacco ingredients on smoke chemistry. Part I: Flavourings and additives, Food and Chemical Toxicology (2004) 42S: S3-S37
- <sup>19</sup> A. Rodgman et Al., Some studies of the effects of additives on cigarette mainstream smoke properties. III. Ingredients reportedly used in various commercial cigarette products in the USA and elsewhere, Beitr. Tabakforsch. Int. (2004) 21:47-104
- <sup>20</sup> M. Akpınar-Elci et Al., Letter to the editor, Crit Rev Toxicolo. (2014) 44(7):638-639
- <sup>21</sup> S. Pierce et Al., Letter to the editor, Crit Rev Toxicolo. (2014) 44(7):640-641
- <sup>22</sup> S. Clark and C. K. Winter, Diacetyl in Foods: A Review of Safety and Sensory Characteristics, Comprehensive Reviews in Food Science and Food Safety (2015) 14:634-643