



PMI RESEARCH & DEVELOPMENT

THS Additional Safety Data Report

Tobacco Heating System / iQOS

Appendix 6 Post-marketing Cumulative Summary Tabulations

Report Number: PMI_SURV_2016_SSR03

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Cumulative tabulation for Serious/Non-Serious Spont all THS Regular

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Dec-2015

Advanced Condition used in this report:

Advanced Condition: Ser/Non-Serious Spont all THS Regular (Created by nicole.miller)

Query Set Selection Criteria:

Report Type=Spontaneous INTERSECT

JCo - 2.4 Regular THS Ingredients

Advanced Conditions used in this query set:

Advanced Condition: Report Type=Spontaneous (Created by nicole.miller)

Selection Criteria:

Case Report Type equal to Spontaneous

Advanced Condition: JCo - 2.4 Regular THS Ingredients (Created by Joshua Cox)

Selection Criteria:

(Ingredient equal to D2 Ron OR

Ingredient equal to Scion 1 Fitz)

Cumulative tabulation for Serious/Non-Serious Spont all THS Regular

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Dec-2015

System Organ Class (SOC)	Preferred Term	Event Seriousness		Total
		No	Yes	
Gastrointestinal disorders	Dyspepsia	3	0	3
	Lip swelling	1	0	1
	Nausea	5	0	5
	Oral discomfort	1	0	1
	Oral mucosal discolouration	1	0	1
	Oral pain	1	0	1
	Salivary hypersecretion	1	0	1
	Vomiting	3	0	3
	SubTotal	16	0	16
General disorders and administration site conditions	Chest pain	1	0	1
	Device issue	3	0	3
	Discomfort	1	0	1
	Malaise	3	0	3
	Mucosal induration	1	0	1
	Product odour abnormal	1	0	1
	Pyrexia	1	0	1
	Sensation of foreign body	1	0	1
	SubTotal	12	0	12
Infections and infestations	Abscess oral	1	0	1
	SubTotal	1	0	1

Cumulative tabulation for Serious/Non-Serious Spont all THS Regular

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Dec-2015

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
Injury, poisoning and procedural complications	Thermal burn	2	0	2
	SubTotal	2	0	2
Investigations	Blood pressure increased	1	0	1
	Heart rate increased	1	0	1
	SubTotal	2	0	2
Nervous system disorders	Dizziness	1	0	1
	Dysgeusia	1	0	1
	Headache	4	0	4
	Syncope	0	1	1
	SubTotal	6	1	7
Psychiatric disorders	Agitation	1	0	1
	SubTotal	1	0	1
Respiratory, thoracic and mediastinal disorders	Cough	2	0	2
	Dry throat	2	0	2
	Dyspnoea	1	0	1
	Haemoptysis	1	0	1
	Oropharyngeal pain	1	0	1
	Productive cough	1	0	1
	SubTotal	8	0	8

Cumulative tabulation for Serious/Non-Serious Spont all THS Regular

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Dec-2015

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
Skin and subcutaneous tissue disorders	Urticaria	1	0	1
	SubTotal	1	0	1
Total		49	1	50

Cumulative Tabulation Serious/Non-Serious Spont All THS Menthol

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Dec-2015

Advanced Condition used in this report:

Advanced Condition: Ingredient All THS Menthol (Created by nicole.miller)

Query Set Selection Criteria:

Report Type=Spontaneous INTERSECT

All THS Menthol Ingredients

Advanced Conditions used in this query set:

Advanced Condition: Report Type=Spontaneous (Created by nicole.miller)

Selection Criteria:

Case Report Type equal to Spontaneous

Advanced Condition: All THS Menthol Ingredients (Created by nicole.miller)

Selection Criteria:

Ingredient equal to D1 Vinny High Menthol OR

Ingredient equal to D1 Kaiden OR

Ingredient equal to D1 Vinny Low Menthol

Cumulative Tabulation Serious/Non-Serious Spont All THS Menthol

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Dec-2015

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
Eye disorders	Chromatopsia	1	0	1
	SubTotal	1	0	1
Gastrointestinal disorders	Abdominal pain	1	0	1
	Abdominal pain upper	1	0	1
	Diarrhoea	1	0	1
	Glossitis	1	0	1
	Glossodynia	1	0	1
	Lip blister	1	0	1
	Lip swelling	1	0	1
	Nausea	6	0	6
	Oral discomfort	1	0	1
	Oral mucosal discolouration	1	0	1
	Oral pain	1	0	1
	Paraesthesia oral	2	0	2
	Vomiting	2	0	2
	SubTotal	20	0	20
General disorders and administration site conditions	Asthenia	1	0	1
	Chest discomfort	1	0	1
	Device battery issue	1	0	1
	Device damage	1	0	1
	Device issue	4	0	4
	Discomfort	1	0	1
	Fatigue	2	0	2

Cumulative Tabulation Serious/Non-Serious Spont All THS Menthol

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Dec-2015

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
General disorders and administration site conditions	Feeling hot	2	0	2
	Malaise	6	0	6
	Mucosal induration	1	0	1
	Pain	2	0	2
	Product odour abnormal	1	0	1
	Product physical issue	1	0	1
	Product quality issue	1	0	1
	Product taste abnormal	1	0	1
	Sensation of foreign body	1	0	1
	Sluggishness	1	0	1
	SubTotal	28	0	28
Infections and infestations	Abscess oral	1	0	1
	SubTotal	1	0	1
Injury, poisoning and procedural complications	Burn oral cavity	2	0	2
	Burns second degree	1	0	1
	Thermal burn	3	0	3
	Tobacco poisoning	1	0	1
	SubTotal	7	0	7

Cumulative Tabulation Serious/Non-Serious Spont All THS Menthol

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Dec-2015

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
Investigations	Heart rate increased	1	0	1
	SubTotal	1	0	1
Nervous system disorders	Aphonia	1	0	1
	Dizziness	4	0	4
	Dysgeusia	1	0	1
	Headache	5	0	5
	Loss of consciousness	0	1	1
	Tremor	1	0	1
	SubTotal	12	1	13
Psychiatric disorders	Nervousness	1	0	1
	Panic reaction	1	0	1
	SubTotal	2	0	2
Respiratory, thoracic and mediastinal disorders	Cough	2	0	2
	Dry throat	1	0	1
	Dyspnoea	1	0	1
	Laryngeal discomfort	1	0	1
	Oropharyngeal pain	1	0	1
	Productive cough	2	0	2
	Throat irritation	1	0	1
	SubTotal	9	0	9

Cumulative Tabulation Serious/Non-Serious Spont All THS Menthol

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Dec-2015

System Organ Class (SOC)	Preferred Term	Event Seriousness		
		No	Yes	Total
Skin and subcutaneous tissue disorders	Blister rupture	1	0	1
	SubTotal	1	0	1
Total		82	1	83

Cumulative Tabulation Serious/Non-Serious Spontaneous iQOS Unspecified

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Dec-2015

Advanced Condition used in this report:

Advanced Condition: Ingredient iQOS (unspecified) (Created by nicole.miller)

Query Set Selection Criteria:

Report Type=Spontaneous INTERSECT

iQOS (unspecified)

Advanced Conditions used in this query set:

Advanced Condition: Report Type=Spontaneous (Created by nicole.miller)

Selection Criteria:

Case Report Type equal to Spontaneous

Advanced Condition: iQOS (unspecified) (Created by nicole.miller)

Selection Criteria:

Product Name equal to iQOS (unspecified)

Cumulative Tabulation Serious/Non-Serious Spontaneous iQOS Unspecified

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Dec-2015

System Organ Class (SOC)	Preferred Term	Event Seriousness	
		No	Total
Cardiac disorders	Tachycardia	2	2
	SubTotal	2	2
Gastrointestinal disorders	Abdominal pain upper	1	1
	Gastric disorder	1	1
	Gingival disorder	1	1
	Glossodynia	1	1
	Mouth ulceration	1	1
	Nausea	4	4
	Swollen tongue	1	1
	Vomiting	1	1
	SubTotal	11	11
General disorders and administration site conditions	Adverse event	1	1
	Chest discomfort	1	1
	Device difficult to use	2	2
	Device malfunction	3	3
	Malaise	3	3
	Product odour abnormal	2	2
	Product physical issue	1	1
	Product quality issue	6	6
	Product taste abnormal	1	1
	Unevaluable event	2	2
	SubTotal	22	22

Cumulative Tabulation Serious/Non-Serious Spontaneous iQOS Unspecified

For All Products (Number of Events)

For the Period 01-Jan-1900 Through 31-Dec-2015

System Organ Class (SOC)	Preferred Term	Event Seriousness	
		No	Total
Nervous system disorders	Dizziness	1	1
	Headache	6	6
	Somnolence	1	1
	SubTotal	8	8
Respiratory, thoracic and mediastinal disorders	Cough	8	8
	Dry throat	2	2
	Dysphonia	1	1
	Dyspnoea	1	1
	Laryngeal discomfort	2	2
	Oropharyngeal discomfort	1	1
	Oropharyngeal pain	7	7
	Throat irritation	4	4
	SubTotal	26	26
Skin and subcutaneous tissue disorders	Pruritus	1	1
	SubTotal	1	1
Total		70	70