Appendix A6.1.5.6 Premarket Safety Surveillance

The two following tables present the number of study participants / respondents exposed to various THS versions / variants in market research studies and perception and behavior studies during which adverse events were collected via passive safety surveillance.

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Table 1 THS Product variant Use per Study

Study	Product	Product variant	Sample size
P1_WOT1_KO	THS 2.2 Regular	(b) (4)	357
	THS 2.2 Regular	(b) (4)	605
	THS 2.2 Menthol	(b) (4)	592
Total P1_WOT1_KO	**NA**	**NA**	**1'316**
P1_WOT2_IT	THS 2.2 Regular	(b) (4)	292
	THS 2.2 Menthol	(b) (4)	310
	THS 2.2 Regular and THS 2.2 Menthol[1]	(b) (4)	41
Total P1_WOT2_IT	**NA**	**NA**	**643**
P1_WOT1_DE	THS 2.2 Regular	(b) (4)	298
	THS 2.2 Regular	(b) (4)	295
Total P1_WOT1_DE	**NA**	**NA**	**593**
P1_WOT1_CH	THS 2.2 Regular	(b) (4)	344
	THS 2.2 Menthol	(b) (4)	236
Total P1_WOT1_CH	**NA**	**NA**	**580**
P1_BT1_RU	THS 2.4 Regular	(b) (4)	309
	THS 2.4 Regular	(b) (4)	302
Total P1_BT1_RU	**NA**	**NA**	**611**
P1_BT1_IT	THS 2.2 Regular	(b) (4)	206
	THS 2.2 Regular	(b) (4)	211
	THS 2.2 Regular	(b) (4)	210
	THS 2.2 Regular	(b) (4)	209
	THS 2.2 Menthol	(b) (4)	211
Total P1_BT1_IT	**NA**	**NA**	**1'047**
THS_PBA_07_US	THS 2.2 Regular	(b) (4)	441
	THS 2.2 Menthol	(b) (4)	512
	THS 2.2 Regular and THS 2.2 Menthol[2]	(b) (4)	205
Total THS_PBA_07_US	**NA**	**NA**	**1'158**

[1] Respondents used both THS regular and THS Menthol.

[2] Respondents used both THS regular and THS Menthol.

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Table 2 Overall THS Products Use in Pre-marketing Studies

Product	Product variant	Sample size
THS Regular	(b) (4)	2'237
	(b) (4)	1'842
Total THS Regular	**NA**	**4'079**
THS Menthol	(b) (4)	**1'650**
	(b) (4)	211
Total THS Menthol	**NA**	**1'861**
THS Regular and THS Menthol	(b) (4)	246
Total THS Product Use		**6'186**

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