FIT OR UNFIT - ELIMINATE THE UNCERTAINTY

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OVERVIEW

- Iliminating Uncertainty and Subjectivity
 - Fitness Guidelines
 - Additions
 - Fenaroli's Use Levels
 - Worksheet
- Ourrent Method Development
- Formulas Online

FITNESS GUIDELINES

GUIDELINES

- Additions to Guidelines:
 - Anise Oil
 - Fennel Oil
 - Tartaric Acid
 - Triacetin
 - Washed Extracts
 - 2% Total Flavor Chemicals
 - Citric Acid
 - Propylene Glycol

With mitigating ingredients

- Randomly selected tasted samples back to 1991
- Collected and compiled formula information
 - Normalized to 15% abv
- Compared to published use rate in <u>Fenaroli's Handbook of Flavor Ingredients</u>

Oetermined:

- Any product containing at least one ingredient present at **5X or greater** than the max use level is unfit for beverage purposes
- Guideline can be used with products containing mitigating ingredients

Created an excel database

- FEMA GRAS chemicals
- Max Use Rate
 - Highest value (alcohol and nonalcoholic beverages)

BENZYL ACETOACETATE

Synonyms: Benzyl acetyl acetate; Benzyl β-ketobutyrate; Benzyl 3-oxobutanoate; Acetoacetic acid, benzyl ester (8CI); Benzyl acetylacetate; Benzyl 3-oxobutanoate; Butanoic acid, 3-oxo-, phenylmethyl ester (9CI); Phenylmethyl 3-oxobutanoate

CAS No.:	5396-89-4	FL No.:	09.406	FEMA No.:	2136	NAS No.:	2136
CoE No.:	244	EINECS No .:	226-416-4	JECFA No .:	848		

Description: Benzyl acetoaceate has a sweet, floral, fresh, balsamic, fruity odor similar to that of ethyl acetate. Individual: 0.00000149 mg/kg/day

Consumption: Annual: <1.00 lb

Regulatory Status: CoE: Used provisionally. Bev.: 3 ppm; Food: 10 ppm

FDA: 21 CFR 172.515

FDA (other): n/a

JECFA: ADI: Acceptable; No safety concern at current levels of intake when used as a flavoring agent (2001).

Trade association guidelines: FEMA PADI: 4.791 mg **Empirical Formula/MW:**

IOFI: n/a

C11H12O3/192.22

о сн₃-С-сн₂-С-о-сн₂-

Specifications: (Burdock, 1997)

Appearance	Oily liquid
Melting point	Approx. 240°C (162-164°C at 16 mmHg)

Soluble in alkali solutions at room Solubility temperature

Usual

16.00

3.00

14.60

Max.

27.56

5.81

22.33

Reported uses (ppm): (FEMA, 1994)

Usual	Max.	Food Category
2.00	5.00	Gelatins, puddings
27.09	43.49	Nonalcoholic beverages
19.00	37.45	Soft candy
11.02	22.21	
	2.00 27.09 19.00	2.00 5.00 27.09 43.49 19.00 37.45

Synthesis: By heating ethyl acetoacetate and benzyl alcohol to 160°C. Aroma threshold values: n/a Taste threshold values: n/a Natural occurrence: Reported found in litchi (Litchi sinensis Sonn.).

Calculation Spreadsheet

- Enter total weight
- Total Alcohol (box #10)
- FEMA #
- Weight of ingredient

Flavor Unfitness Worksheet

Formula Information:	
Total Weight	
Alcohol content (high end of box #10)	

Don't know how to use this worksheet? See the instructions below!

FEMA #	Ingredient	Weight of ingredient	ppm in flavor	ppm @ 15% ABV	MAX Use Level	Factor higher MAX Use Level	Fit or Unfit?	Remarks
	-		-	-	-	-	-	-
	-		-	-	-	-	-	-
	-		-	-	-	-	-	-
			-	-	-	-	-	-
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	<u>-</u>		-	-	-	-	-	-
	-		-	-	-	-	-	-

Flavor Unfitness Worksheet

Formula Information:	
Total Weight	100
Alcohol content (high end of box #10)	33.4

Don't know how to use this worksheet? See the instructions below!

FEMA #	Ingredient	Weight of ingredient	ppm in flavor	ppm @ 15% ABV	MAX Use Level	Factor higher MAX Use Level	Fit or Unfit?	Remarks
2427	ETHYL BUTYRATE	0.04	400.0	179.6	37.88	4.7	FIT	-
2560	2-HEXENAL	0.01	100.0	44.9	6.7	6.7	UNFIT	-
	<u> </u>		0.0	0.0	-	-	-	-
			0.0	0.0	-	-	-	-
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	-		0.0	0.0	-	-	-	-

'FIT' or 'UNFIT' will display after values are entered.

'FIT (Max Use Level is higher)' appears in the Remarks column when the Max Use Level is higher than the ppm of the ingredient at 15% ABV.

Flavor Unfitness Worksheet

Formula Information:	
Total Weight	100
Alcohol content (high end of box #10)	45.9

Don't know how to use this worksheet? See the instruction elow!

FEMA #	Ingredient	Weight of ingredient	ppm in flavor	ppm @ 15% ABV	MAX Use Level	Factor higher MAX Use Level	Fit or Unfit?	Remarks
2127	BENZALDEHYDE	0.01	100.0	32.7	57.55	-	_	FIT (Max Use Level is higher)
	-		0.0	0.0	-	-	-	-
	-		0.0	0.0	-	-	-	-
	-		0.0	0.0	-	-	-	-
	-		0.0	0.0	-	-	-	•
	-		0.0	0.0	-	-	-	-
	-		0.0	0.0	-	-	-	-
	-		0.0	0.0	-	-	-	-
	-		0.0	0.0	-	-	-	
	_		0.0	0.0	-	-	-	-
	-		0.0	0.0	-	-	-	-
	-		0.0	0.0	-	-	-	-
	-		0.0	0.0	-	-	-	-
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	-		0.0	0.0	-	-	-	¥

Materials excluded from this guideline:

- Ingredients with established guidelines
 - Ex: PG, ethyl acetate, etc...
- Materials found to be fit at 1% or 0.1%
 - Ex: isoamyl acetate, limonene
- TTB and FDA limited ingredients

FEMA #	Ingredient	Weight of ingredient	ppm in flavor	ppm @ 15% ABV	MAX Use Level	Factor higher MAX Use Level	Fit or Unfit?
2414	ETHYL ACETATE		0.0	0.0	REMOVED	о 1 	-
2656	MALTOL		0.0	0.0	REMOVED	-	-
2633	LIMONENE (d,I-, and dI-)		0.0	0.0	REMOVED	-	-
2489	FURFURAL		0.0	0.0	REMOVED	-	-
2940	PROPYLENE GLYCOL		0.0	0.0	REMOVED	-	-

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10	Flavor Unfitness Worksheet	-	
13	Formula Information:	Don't know how to use this worksheet? See the instructions below!	
10	Total Weight Alcohol content	_	

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2. Enter the FEMA number. If you do not know it, search the tab 'GRA5 Materials.' Once the FEMA # is entered, the name of the ingredient will automatically appear.

3. Enter the weight of the ingredient. NOTE: The units of total weight and individual ingredient must match.

4. All other calculations will be done automatically. If the amount of the ingredient is at least 5X the Max Use Rate, then the final product is unfit.

11 Other Guidelines:

Worksheets for the other guidelines found in the Drawback Tutorial are on the other tabs in this worksheet. Use the appropriate tab based on the units used.

・ トキ Flavor Unfitness Worksheet 、 Component W5 (bi-gal) 、 Component W5 (o-mt.) 、 GRAS Material 、 Car

GRAS MATERIALS TAB

<u>Hint:</u> Use ctrl-f (find function) to quickly search the list.

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559	8012-89-3	2126	Beeswax	Beeswax, white (Apis mellifera L.)						
560	8012-89-3	2126	Beeswax, white (Apis mellifera L.)		Find and Replace				? 🛛	
561	8012-89-3	2126	Cire d'abeille absolute	Beeswax, white (Apis mellifera L.)	Find Replace					
562	100-52-7	2127	Benzaldehyde		Find what: benzal	dehvde			•	
563	100-52-7	2127	Benzenecarbonal	Benzaldehyde						
564	100-52-7	2127	Benzene carboxaldehyde	Benzaldehyde						
565	100-52-7	2127	Benzenemethylal	Benzaldehyde					Options >>	
566	100-52-7	2127	Benzoic aldehyde	Benzaldehyde			Find All	Find Next	Close	1
567	100-52-7	2127	Bitter almond oil, synthetic	Benzaldehyde				Linu wext	Close	J
568	1125-88-8	2128	Benzaldehyde dimethyl acetal		L					
569	1125-88-8	2128	Benzene, (dimethoxymethyl)-	Benzaldehyde dimethyl acetal						
570	1125-88-8	2128	alpha,alpha-Dimethoxytoluene	Benzaldehyde dimethyl acetal						
571	1319-88-6	2129	Benzaldehyde, cyclic acetal with glycerol	Benzaldehyde glyceryl acetal						
572	1319-88-6	2129	Benzaldehyde glyceryl acetal							
573	1319-88-6	2129	Benzalglycerin	Benzaldehyde glyceryl acetal						
574	1319-88-6	2129	1,3-Dioxolane-4-methanol, 2-phenyl-	Benzaldehyde glyceryl acetal						
575	1319-88-6	2129	4-Hydroxymethyl-2-phenyl-m-dioxolane	Benzaldehyde glyceryl acetal						
576	1319-88-6	2129	5-Hydroxy-2-phenyl-1,3-dioxane	Benzaldehyde glyceryl acetal						
577	1319-88-6	2129	2-Phenyl-1,3-dioxan-5-ol	Benzaldehyde glyceryl acetal						
578	1319-88-6	2129	2-Phenyl-m-dioxan-5-ol	Benzaldehyde glyceryl acetal						
579	2568-25-4	2130	Benzaldehyde propylene glycol acetal							
580	2568-25-4	2130	1,3-Dioxolane, 4-methyl-2-phenyl-	Benzaldehyde propylene glycol acetal						
581	2568-25-4	2130	4-Methyl-2-phenyl-1,3-dioxolane	Benzaldehyde propylene glycol acetal						
	2568-25-4	2130	4-Methyl-2-phenyl-m-dioxolane	Benzaldehyde propylene glycol acetal						
583	65-85-0	2131	Benzenecarboxylic acid	Benzoic acid						
	65-85-0	2131	Benzoic acid							
	65-85-0	2131	Dracylic acid	Benzoic acid						
	119-53-9	2132	Benzoin							
	119-53-9	2132	Benzoyl phenyl carbinol	Benzoin						
	119-53-9	2132	Ethanone, 2-hydroxy-1,2-diphenyl-	Benzoin						
	119-53-9	2132	alpha-Hydroxy-alpha-phenylacetophenone	Benzoin						
590	119-53-9	2132	2-Hydroxy-2-phenylacetophenone	Benzoin						
	9000-05-9	2133	Benzoin resin	Benzoin resinoid						
592	9000-05-9	2133	Benzoin resinoid							
	9000-05-9	2133	Gum benzoin	Benzoin resinoid						
	119-61-9	2134	Benzophenone							
14 4 1	Flavor Ur	nfitness Wor		L) _ GRAS Materials 🖓 🚺 🔤						
Ready								🔲 🛄 115%		🕀

COMPONENT WS TAB

available for lbs/gal and g/mL

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	А	В	С	D	E	F	G	Н	1	J	К	L	М	N	0	Р	Q		
103	M																		
104	Vanillin	-	A at 95% v/v eth Minimum Value	nanol															
105		(upper end of range in item 10)	Needed to Make Product Unfit		Amount of Vanillin (pounds)	Volume of Final Product (gallons)	av.oz. / gal of Vanillin	Unfit?											I
106			0.000				-	-											I
107	Washed Extracts	6.33% by weig	abt at 95% v/v	ethe	nol														
108	Washed Extracts		Minimum Value	ettiai		Waight of Final			[
109		(upper end of range in item 10)	Needed to Make Product Unfit (wt%)		Amount of Oil (pounds)	Weight of Final Product (pounds)	% by weight of Oil	Unfit?											
110			0.00				-	-											
111																			I
112	Flavor Chemicals unfit at 1%	1% by weight	t at 95% v/v eth	hanol															
113		Alcohol Content (upper end of range in item 10)	Minimum Value Needed to Make Product Unfit		Amount of Flavor Chemical (pounds)	Weight of Final Product (pounds)	% by weight of Flavor Chemical	Unfit?											
114			0.158				-	-											
		(cannot be scale	ed below 15% alco	ohol)															
115																			
116	Total Flavor Chemicals	2% by weight	t at 95% v/v eth	nanol	(chemicals n	nust be listed on t	the 1% list)												
		(upper end of range in item	Minimum Value Needed to Make Product		Amount of Flavor Chemicals (pounds)	Weight of Final Product (pounds)	% by weight of Flavor Chemicals	Unfit?											
117		10)	Unfit		(pounds)	(pounda)		<u> </u>											
118		(cannot be seed	0.316 ad below 15% alco	ohell			-	-											
119		(cannot be scale	u Delow 10% alco	51101)															
120 121																			
122 123																			U
14 4	Flavor Unfitness	Worksheet	Component WS	(lbs-g	al) Component	: WS (g-mL) 📈 (GRAS Materials	2		[◀									
Ready	/ 🛅														90%	Θ		-+	:

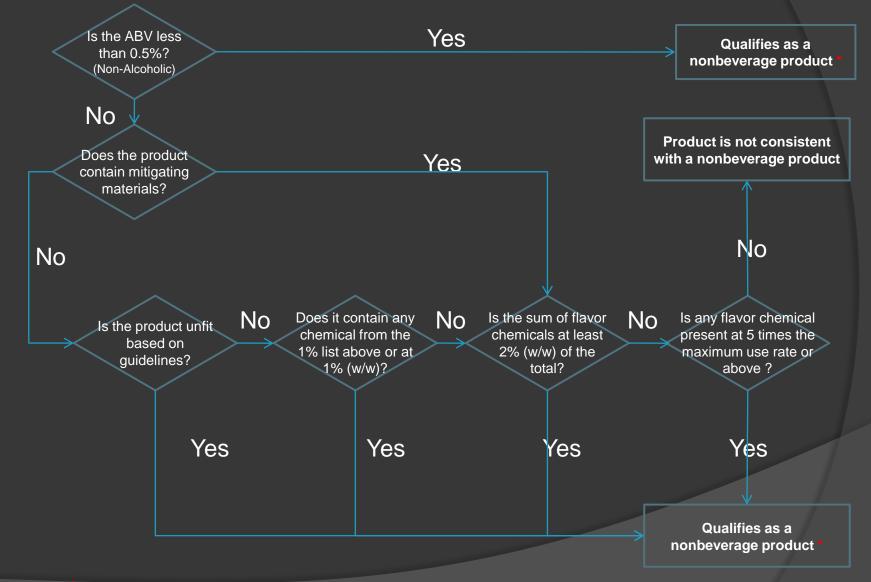
		Formula a	pproval: OMB No. 1	512-0095 (09/30/98
DEPARTMENT OF	THE TREASU	RY		1. FORMULA NUMBER
BUREAU OF ALCOHOL, TO	DBACCO AND	FIREARMS		15
FORMULA AND PROCESS FOR	R NONBEVER	RAGE PRO	DUCT	2. KIND (e.g. Alcohol, Rum)
(See instructions attached-Prepare in trip	licate, except if ma	nufactured abro	oad)	PROOF OF SPIRITS ON WHICH
3. NAME OF PRODUCT.	4. CHECK	IF SAMPLE	5. NUMBER OF DAYS TO	DRAWBACK WILL BE CLAIMED.
The contraction of a second state of a second state	WILL BE	SUBMITTED	COMPLETE PROCESS	Alcohol 190 proof
Natural Raspberry Flavor WONF			1	
6. NAME OF THE MANUFACTURER & ADDRESS WHERE P	RODUCTS WILL	7. CHECK K	IND OF PRODUCT:	8. FORMULAS SUPERSEDED.
BE PRODUCED (if multiple production sites, list other addresse	es on reverse).	MEDICIN	E/ MEDICINAL PREPARATION	
Company A		FLAVOR/ FL	AVORING EXTRACT	
6000 Ammendale Rd		FOOD PR		
Beltsville, MD 20705		9. ELIGIBLE	ABSOLUTE ALCOHOL	10. ALCOHOL CONTENT BY VOLUME
		VOLUME	USED. (See instructions)	OF FINISHED PRODUCT.
			42.6%	42.6 +/- 2.0%
S D. does E. Are A	ATE PARTS PER MILL YNTHETIC MALTOL 8 PRODUCT CONTAIN A COL	LOR ADDITIVE?	OF: VANILLIN ETHYL MALTOL IF YES, WHICH? MTHOUT LIMITATION OR RESTRICTION	ETHYL VANILLIN ? (YES OR NO)
13. FORMULA AND PROCESS (Use Additional Space on Reverse if Necessary).				
Ethanol 190 proof			35 lbs (5.15 gal)	
Glycerine			25 lbs	
Citric Acid			9.4 lbs	
Raspberry Essence (purchased 3% abv	/)		1 lb (.13 gal)	
Natural Acetic Acid			0.5 lbs	
Nat Ethyl Butyrate (0.04 lbs) and other	natural este	arc	0.1 lbs	
Water	naturai cote		29 lbs	
anarci			23 105	
	Theoretic	cal Yield	100 lbs (11.5 ga	I)
Simple Mixture				

Citric Acid Ethanol $\leq 30\%$ v/v – acid must be $\geq [(0.1 \times \text{ethanol }\%) + 0.5]$ (g/100 mL)

Ethanol > 30% v/v – acid must be \geq [0.1 × ethanol %] (g/100 mL)

Ethanol ≤ 30% ∨/∨	Alcohol Content (upper end of range in item 10)	Minimum Value Needed to Make Product Unfit 0.500		Amount of Citric Acid (pounds)	Volume of Fina Product (gallons)	l g / 100 m L Citric Aci		Unfit?		Needed (if product contains mitigating ingredients) 1.000	Unfit? -	
	Alcohol Content (upper end of range in item 10)	Minimum Value Needed to Make Product Unfit		Amount of Citric Acid (pounds)	Volume of Fina Product (gallons)	l g / 100 m L Citric Aci		Unfit?		Needed (if product contains mitigating ingredients)	Unfit?	
Ethanol > 30% ∨/∨	44.6	4.460		9.4	11.5	9.7947202	35	YES		8.920	YES	
	Beltsville 11. IF MA ELIGIBLE	IV A nmendale Rd e, MD 20705 DE WITH RECOVERED SPIRI PLUS RECOVERED ABSOLU ME USED. (See instructions).		COHOL A DOES PRODUCT COM B. DOES PRODUCT (Yes or No) C. STATE PARTS SYNTHETIC M	DEFINITION IN PRODUCT	ABSOLUTE ALCOHOL JSED. (See instructions) 42.6% HOLIC BEVERAGES. (OR NO) 1% ARTIFICIAL FLAVORINGE	10.	ALCOHOL CONTE OF FINISHED PRO 42.6 +/- : 'anilin, Ethyl Vanillin,M	DUCT. 2.0%			
	Ethane Glycer Citric Raspb Natura	Acid perry Essence (purc al Acetic Acid hyl Butyrate (0.04 II	hase	ed 3% abv) and other natural	esters	35 lbs (5.15 ga 25 lbs 9.4 lbs 1 lb (.13 gal) 0.5 lbs 0.1 lbs 29 lbs	1)	JR NO)				
	Simple	e Mixture										

NONBEVERAGE FITNESS DETERMINATION PROCESS



Submissions must also meet other TTB regulations regarding name, GRAS ingredients and alcohol content calculations

CURRENT METHOD DEVELOPMENT

CURRENT METHOD DEVELOPMENT

- Vanillin/ Ethyl Vanillin/ Maltol / Ethyl Maltol
- Vanilla Extracts
- Caffeine
- Ethyl Isobutyrate
 2-Methyl Butyrate
 Ethyl Butyrate
 Myrcene
 Limonene
 cis-3-Hexenol
 Cinnamyl Alcohol

Linalool Menthol Ethyl Benzoate Benzyl Alcohol Thymol Anisyl Alcohol

CURRENT METHOD DEVELOPMENT

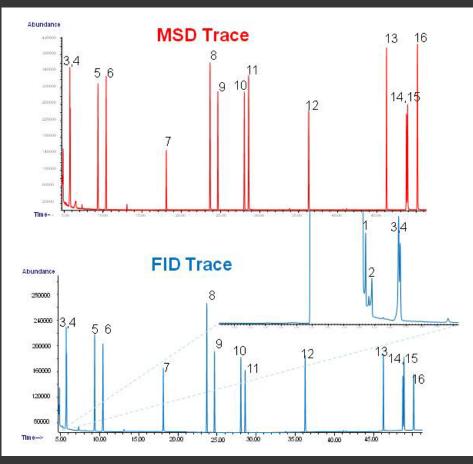
- Multi-lab method validation
- I3 commonly used flavor chemicals
- Analysis for compliance and fitness determination
- Contact: Ed Limowski
 - edward.limowski@ttb.gov

INSTRUMENTATION AND EXPERIMENTAL CONDITIONS

Gas chromatograph Autosampler Autosampler mode Injection volume Inlet Oven profile Post run Backflush inlet flow Backflush pressure splitter Column Column dimensions Presssure at splitter Restrictor 1 (to FID) Restrictor 2 (to MSD) Mode MSD Detector **FID** Temperature FID Detector flows Solvent delay-(MSD) Scan-(MSD)

Agilent 6890 Gerstel MPS 2 Liquid 1 μL 250 °C; 5:1 split 40 °C 2'; 3 °C/min 240 °C; 1.0' 240 °C for 5 min 0.1 mL/min 60 PSI Phenomenex ZB-WAXplus 30 m × 0.25 mm × 0.25 µm 20 PSI 0.18 µm ID ; 2.128 m 0.18 µm ID ; 2.886 m Constant flow 1 mL/min Agilent MSD 5975 Inert 300 °C H_2 30 mL/min, air 400 mL/min 4.67 min 30-300 amu

SAMPLE CHROMATOGRAMS



Total Ion Chromatogram (TIC, red trace) and chromatogram (FID, blue trace) for 125 ppm standard, 1 μl single injection. 1 Ethyl Isobutyrate; 2 2-Methyl Butyrate; 3 Deuterated Ethyl Butyrate (IS); 4 Ethyl Butyrate; 5 Myrcene; 6 Limonene, 7 cis-3-Hexenol ; 8 2-Nonanol (IS); 9 Linalool; 10 Menthol; 11 Ethyl Benzoate 12 Benzyl Alcohol;13 Thymol; 14 Anisyl Alcohol; 15 Cinnamyl Alcohol, 16 3',4'-(Methylenedioxy)-acetophenone (IS)

FUTURE WORK

More method development of flavor chemicals

Borneol 1-decanol 1-dodecanol Geraniol 1-heptanol 1-hexanol cis/trans isoeugenol cis-6-nonen-1-ol 1-nonanol 1-octanol 2-octanol 1-octen-3-ol

- May also be included in multi-lab validation
- Materials found in both Drawback and SDA products
- Stability of Flavor Chemicals

- Online submission of Drawback and SDA formulas
- Automatic calculations of eligible and total alcohol
- Status tracking through system
 - In Progress
 - Needs Correction
 - Complete
- Automatic notification of completed formula
- Contact chemist assigned formula in system

- Various formula types
 - Simple Mixture
 - Filtration
 - Washed Extract
 - Dietary Supplement
 - Other no automatic calculations

Alcohol Calculations Automatic

Win Formed Sample Company Comment Description Paper Submission Summary O Measurements Used: Process Type: O Box #9 Simple Mission Acohol Contains Of Finished Product: Supproved English of Duba contents Eligible Absolute Alcohol Used: Supproved Type: O Box #10 duct not the same as declared alcohol content? Density of Finished Product: Value: Vector (a) Wetcerr (a) Wetcerr (a) (www.wetcerr (a) Volume (at.) Volume (at.) Volume (at.) (www.wetcerr (a) (w						
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Ethyl Vanillin: Synthetic Maltol: Ethyl	Actual Yield: Alcoholic Beverage Use @ Is Finished Product to be Used In Al Product Contains Natural Flavoring	(Low) • • 100 cohol Beverages?	(нісн)	(LOW)	Parts Per	
Vanillin: Synthetic Maltol: Ethyl	Actual Yield: Alcoholic Beverage Use Is Finished Product to be Used In Al Product Contains Natural Flavoring Product Contains > 0.1% Artificial Fl	(Low) • • 100 cohol Beverages?	(нісн)	(LOW)	Parts Per	
Maltol: Ethyl	Actual Yield: Alcoholic Beverage Use @ Is Finished Product to be Used In Al Product Contains Natural Flavoring Product Contains > 0.1% Artificial Fl Product Contains Color Additive	(Low)	(нісн)	(LOW) (LOW) TTB INGREDIENT Synthetic Vanillin:	Parts Per	
Ethyl	Actual Yield: Alcoholic Beverage Use @ Is Finished Product to be Used In Al Product Contains Natural Flavoring Product Contains > 0.1% Artificial Fl Product Contains Color Additive	(Low)	(нісн)	(Low) 0 10 <td>Parts Per</td> <td></td>	Parts Per	
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Does product contai	n eligible alcohol?						
ELIGIBLE ALCOHOL 🛛							
	WEIG	нт (LB)	VOLUME (GAL)	DENSITY (LB/GAL)	Ассоно	L(%)	
Ethanol 190 Proo	<u>f</u> 54.2		7.98	6.8	95		
			Add	Delete	1		
Does product contai	n disapproved intermedi	ates?			2		
Does product contai	n ineligible alcohol?						Box #13
Ionalcoholic Comp	onents 0						information
	n ingredients by group?						
	n individual solid ingredie	nts?					
NDIVIDUAL INGREDIENTS	(Solids) 🛛						
NATURAL/ARTIFICIAL	Маме	FEMA #	ADDITIONAL I	NFORMATION		WEIGHT (LB)	
Neither	Citric Acid		-			6.5	
Natural	<u>Citral</u>	2303	-			0.6	
	Add	Del	ete				
Does product contain	n individual liquid ingredi	ents?					
NDIVIDUAL INGREDIENTS	(LIQUIDS) 🔞						
NATURAL/ARTIFICIAL	NAME	FEMA #		WEIGHT (LB)	VOLUME (GAL)	SOL	
Neither	Propylene Glycol			22.3	2.58		
Neither	<u>Water</u>			16.4	1.97		
			-1-				
	Add	Del	ete				

1.0 release ('uniform' and user registration)

- Winter 2011
- I.1 release (drawback and SDA)
 - Summer 2011
- User Testing
 - Volunteers needed for external/submitter user testing
 - Winter/Spring 2011
 - Contact Rachel Sanderoff
 - <u>rachel.sanderoff@ttb.gov</u>

