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# Eugenol

## Taiwan Reporting Repository

September 2026

Prepared by British American Tobacco

| Version | Revision Description                                            | Evaluator  | Date        |
|---------|-----------------------------------------------------------------|------------|-------------|
| 1       | Integration of data repository into Taiwan reporting repository | I Williams | 07 Sep 2026 |
|         |                                                                 |            |             |

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## Identification & Characterisation

Table 1. Identification & Characterisation details of **Eugenol**.

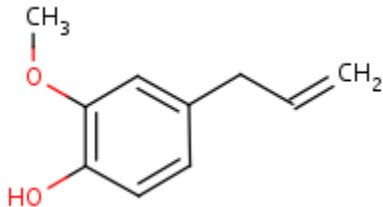
|                           |                                                                                    |         | Reference            |
|---------------------------|------------------------------------------------------------------------------------|---------|----------------------|
| Ingredient Name           | Common Name                                                                        | Eugenol | PubChem <sup>1</sup> |
| Synonyms of Common Name   | 2-Methoxy-4-(2-propenyl)-phenol<br>4-Allyl-2-methoxy-phenol                        |         | PubChem <sup>1</sup> |
| CAS Number                | 97-53-0                                                                            |         | PubChem <sup>1</sup> |
| EINECS Number             | 202-589-1                                                                          |         | PubChem <sup>1</sup> |
| Aroma Chemical or Natural | Aroma Chemical                                                                     |         |                      |
| Molecular Formula         | C <sub>10</sub> H <sub>12</sub> O <sub>2</sub>                                     |         | PubChem <sup>1</sup> |
| Structural Formula        |  |         | PubChem <sup>1</sup> |
| Canonical SMILE           | C=CCc1ccc(OC)c(OC)c1                                                               |         | PubChem <sup>1</sup> |
| Molecular Weight          | 164.2 g/mol                                                                        |         | PubChem <sup>1</sup> |
| Cramer Class              | Class I                                                                            |         | JECFA <sup>2</sup>   |

Table 2. Physico-chemico properties of **INGREDIENT NAME**.

|                             |                                                                         |  | Reference                                |
|-----------------------------|-------------------------------------------------------------------------|--|------------------------------------------|
| Melting Point (°C)          | -9.2 to -9.1                                                            |  | Pubchem <sup>3</sup>                     |
| Boiling Point (°C)          | 256 °C<br>252.00 to 253.00 °C. @<br>760.00 mm Hg<br>253.80              |  | Pubchem <sup>1</sup>                     |
| Solubility in Water (g/L)   | 2.46                                                                    |  | PubChem <sup>1</sup>                     |
| Flammability limits (% v/v) | N/A                                                                     |  | PubChem <sup>1</sup><br>EPA <sup>4</sup> |
| (Auto) Ignition Temp. (°C)  | N/A                                                                     |  | PubChem <sup>1</sup><br>EPA <sup>4</sup> |
| Decomposition Temp. (°C)    | When heated to decomposition it emits acrid smoke and irritating fumes. |  | PubChem <sup>1</sup>                     |

<sup>1</sup> <https://pubchem.ncbi.nlm.nih.gov/compound/3314>

<sup>2</sup> WHO | JECFA

<sup>3</sup> <https://pubchem.ncbi.nlm.nih.gov/compound/3314#section=Melting-Point>

<sup>4</sup> <https://comptox.epa.gov/dashboard/chemical/properties/DTXSID9020617>

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|                                                                                      |                                          |                      |
|--------------------------------------------------------------------------------------|------------------------------------------|----------------------|
| Stability                                                                            | Darkens and thickens on exposure to air. | PubChem <sup>1</sup> |
| Vapour Pressure                                                                      | 0.01 mmHg at 68 °F ; 0.03 mmHg at 77 °F  | PubChem <sup>1</sup> |
| Log K <sub>ow</sub>                                                                  | 2.49                                     | PubChem <sup>1</sup> |
| Henry's Law constant (or air-water partition coefficient) (atm m <sup>3</sup> /mole) | 1.69e-6                                  | EPA <sup>4</sup>     |

Table 3. Regulatory or authoritative status of **EUGENOL**

|                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Reference                                    |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
| FEMA Number         | No.2467                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <a href="#">FEMA flavour library</a>         |
| CoE Number          | [171; Category A (may be used in foodstuffs)]                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <a href="#">EC No. 1334/2008 Database</a>    |
| Flavis Number       | 04.003                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <a href="#">EC No. 1334/2008 Database</a>    |
| JECFA Number        | 1529                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <a href="#">JECFA</a>                        |
| ADI                 | 2.5 mg/kg bw/day                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | JECFA, EFSA                                  |
| Intake (EFSA/JECFA) | Reported food-use levels vary by food categor                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | JECFA, EFSA                                  |
| History of Use      | <p>Widely distributed in the plant kingdom, where it is mainly found as a component of essential oils, at concentrations ranging from 0.002 mg/kg (cranberry (<i>Vaccinium macrocarpon</i>), press residue) to 945 g/kg (Cinnamon (<i>Cinnamomum zeylanicum</i>) leaf oil).</p> <p>Naturally present in various herbs and spices from 0-21 ppm (Spanish thyme) to 180,000 ppm (clove flower).</p> <p>Reported uses: usual levels of 0.5 (alcoholic beverages) to 625 ppm (confectionary frosting); maximum levels of 1 (alcoholic beverages) to 814 ppm (miscellaneous foods).</p> <p>Maximum use levels: 1.4-500 ppm (beverages, ice cream, baked goods, gelatins, puddings and chewing gums); up to 2000 ppm (processed meats).</p> | IARC, 1985<br>EFSA, 2011                     |
| FDA                 | <p>Food for human consumption: 21 CFR 184 – Direct food substances affirmed as generally recognized as safe: 184.1257 Clove and its derivatives.</p> <p>Food for human consumption: 21 CFR 177 – Indirect food additives: polymers: 177.2800 Textiles and textile fibers.</p> <p>Animal drugs, feeds, and related products: 21 CFR 582 - Substances affirmed as generally recognized</p>                                                                                                                                                                                                                                                                                                                                              | <a href="#">FDA Substances added to food</a> |

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|                                                                                         | as safe: 582.60 Synthetic flavoring substances and adjuvants.<br>Drugs for human use: 21 CFR 310 – New drugs: 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.                                                                                                                                                                                                                                                                                                                                              |                                                                                   |                                          |                              |                                          |              |      |                                                                                   |  |               |      |                                                                                   |  |                      |
|-----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|------------------------------------------|------------------------------|------------------------------------------|--------------|------|-----------------------------------------------------------------------------------|--|---------------|------|-----------------------------------------------------------------------------------|--|----------------------|
| Substance of Very High Concern (SVHC) Candidate list                                    | Not listed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <a href="#">ECHA SVHC Candidate list</a>                                          |                                          |                              |                                          |              |      |                                                                                   |  |               |      |                                                                                   |  |                      |
| ECHA Authorisation List                                                                 | Not listed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <a href="#">ECHA Authorisation list</a>                                           |                                          |                              |                                          |              |      |                                                                                   |  |               |      |                                                                                   |  |                      |
| ECHA Health hazard classification (see Annex VII for human health hazards) <sup>5</sup> | <div>Classification<div>In alignment with CLP Annex I</div><table><thead><tr><th>Hazard class, category</th><th>Hazard statement code</th><th>Reason(s) for classification</th><th>Affected organ(s) / Route(s) of exposure</th></tr></thead><tbody><tr><td>Eye Irrit. 2</td><td>H319</td><td></td><td></td></tr><tr><td>Skin Sens. 1B</td><td>H317</td><td></td><td></td></tr></tbody></table></div> | Hazard class, category                                                            | Hazard statement code                    | Reason(s) for classification | Affected organ(s) / Route(s) of exposure | Eye Irrit. 2 | H319 |  |  | Skin Sens. 1B | H317 |  |  | <a href="#">ECHA</a> |
| Hazard class, category                                                                  | Hazard statement code                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Reason(s) for classification                                                      | Affected organ(s) / Route(s) of exposure |                              |                                          |              |      |                                                                                   |  |               |      |                                                                                   |  |                      |
| Eye Irrit. 2                                                                            | H319                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  |                                          |                              |                                          |              |      |                                                                                   |  |               |      |                                                                                   |  |                      |
| Skin Sens. 1B                                                                           | H317                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  |                                          |                              |                                          |              |      |                                                                                   |  |               |      |                                                                                   |  |                      |
| IARC classification                                                                     | Group 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <a href="#">IARC</a>                                                              |                                          |                              |                                          |              |      |                                                                                   |  |               |      |                                                                                   |  |                      |
| NTP classification                                                                      | Not Listed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <a href="#">NTP RoC</a>                                                           |                                          |                              |                                          |              |      |                                                                                   |  |               |      |                                                                                   |  |                      |
| EPA classification                                                                      | Not Listed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <a href="#">EPA IRIS</a>                                                          |                                          |                              |                                          |              |      |                                                                                   |  |               |      |                                                                                   |  |                      |
| Endocrine Disruptor Lists                                                               | Not Listed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <a href="#">Endocrine disruptor lists</a>                                         |                                          |                              |                                          |              |      |                                                                                   |  |               |      |                                                                                   |  |                      |
| Occupational limits                                                                     | Not listed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <a href="#">GESTIS</a>                                                            |                                          |                              |                                          |              |      |                                                                                   |  |               |      |                                                                                   |  |                      |
| EU BAP Ingredient                                                                       | Not listed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <a href="#">EU No. 1334/2008</a>                                                  |                                          |                              |                                          |              |      |                                                                                   |  |               |      |                                                                                   |  |                      |
| California Prop 65                                                                      | Not listed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <a href="#">OEHHA</a>                                                             |                                          |                              |                                          |              |      |                                                                                   |  |               |      |                                                                                   |  |                      |
| Oral Allergy/ Intolerance                                                               | Not Listed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <a href="#">EU No. 1169/2011</a>                                                  |                                          |                              |                                          |              |      |                                                                                   |  |               |      |                                                                                   |  |                      |

<sup>5</sup> According to the human health (including physical hazard) classifications in the ECHA C&L Inventory (<http://echa.europa.eu/information-on-chemicals/cl-inventory-database>); environmental classifications are beyond the scope of this monograph.

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## Taiwan Referencing Convention

Each of the following sections requires a *brief description of reference, formal citation, and 'A' number designated*. Only one reference needs to be provided per section (essentially, presence or absence of data).

If ingredient specific references cannot be identified for any of the sections below, insert 'N/A' where appropriate.

Each reference cited in the following sections must have a unique identifier, starting with an 'A', followed by 4 digits. This is the prescribed format of Taiwan's regulatory authority.

Once saved on a local drive and named according to convention, references must be stored in the following folder location on SharePoint:

### Taiwan 'A' References

As of 31<sup>st</sup> December 2024, the latest reference was saved as A0690. The next reference identified for any given Taiwan Reporting Repository must follow chronologically, A0691, A0692, etc. Please check the Taiwan 'A' references folder<sup>6</sup> on SharePoint for the next unique identifier in sequence.

Once the following sections are completed, with references collated. All references must be merged into one pdf. This pdf should then be titled using the same naming convention described above (i.e. the next 4 digit 'A' number in sequence).

It is this final 'A' reference that must be provided to Tox Enablers, along with a completed Reporting Repository.

Upon completion, the Evaluator is responsible for saving a finalised Taiwan Reporting Repository in the Taiwan Reporting folder<sup>7</sup>.

All previous Taiwan Reporting Repositories are saved in the following folder on the H Drive:

<H:\Group\R&D\S&RA\Ings Comp Team\Disclosure RD158\2017\Taiwan\Tox Profiles>

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<sup>6</sup> <https://bat.sharepoint.com/:f:/r/sites/GBIN-CPS900/Shared%20Documents/Tox%20Reporting/Taiwan%20Reporting/Taiwan%20%27A%27%20References?csf=1&web=1&e=uon5Cu>

<sup>7</sup> <https://bat.sharepoint.com/:f:/r/sites/GBIN-CPS900/Shared%20Documents/Tox%20Reporting/Taiwan%20Reporting?csf=1&web=1&e=n4SkXb>

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## Dermal/ Inhalation Carcinogenicity

Brief description of reference:

Dermal carcinogenicity studies in mice did not demonstrate clear evidence of carcinogenic activity for eugenol. In a 63-week skin painting study, repeated dermal application of eugenol alone did not induce tumours; however, a weak tumour-promoting effect was observed in a small number of animals pre-treated with dimethylbenzanthracene (DMBA). A second carcinogenicity study involving intraperitoneal administration of eugenol to neonatal mice also found no evidence of carcinogenicity. Both studies were considered limited when compared with modern carcinogenicity testing guidelines

Formal citation:

Miller EC, Swanson AB, Phillips DH, Fletcher TL, Liem A, Miller JA. (1983). Structure-Activity Studies of the Carcinogenicities in the Mouse and Rat of Some Naturally Occurring and Synthetic Alkenylbenzene Derivatives Related to Safrole and Estragole.

Cancer Research 43(3):1124-1134

'A' number designated:

A0701

## Inhalation Studies

Brief description of reference:

A 4-hour whole-body aerosol inhalation study in rats reported an LC<sub>50</sub> greater than 2580 mg/m<sup>3</sup>. Clinical signs were consistent with respiratory irritation, with no treatment-related gross pathological or microscopic pulmonary effects observed.

Formal citation:

Clark, G.C. Acute inhalation toxicity of eugenol in rats. Arch Toxicol 62, 381–386 (1988). <https://doi.org/10.1007/BF00293627>

'A' number designated:

A0702

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## In vitro Toxicology

Brief description of reference:

A substantial in vitro genotoxicity database is available for eugenol. Most bacterial reverse mutation assays were negative, whereas some mammalian cell assays produced positive or equivocal findings, generally at cytotoxic concentrations. Overall interpretation by expert review bodies considered the weight of evidence alongside negative in vivo studies.

Formal citation:

Safety evaluation of certain flavouring agents; European Food Safety Authority (2009). Flavouring Group Evaluation 60 (FGE.60): Consideration of eugenol and related hydroxyallylbenzene derivatives evaluated by JECFA. EFSA Journal, 7(2), 965.

'A' number designated:

A0703

## Other Toxicological Information

Brief description of reference:

Eugenol is a recognised skin sensitiser and skin/eye irritant. Human patch-test studies and animal sensitisation studies demonstrate sensitisation potential, and the RIFM review established a NESIL of 5900 µg/cm<sup>2</sup>.

Formal citation:

Api, A.M. et al. (2022). Update to RIFM fragrance ingredient safety assessment, eugenol, CAS Registry Number 97-53-0. Food and Chemical Toxicology, 163, 113027.

'A' number designated:

A0704

## Pyrolysis

Brief description of reference: N/A. No ingredient-specific reference identified.

Formal citation: N/A

'A' number designated: N/A

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## Reproductive & Developmental Toxicity

Brief description of reference: N/A. No ingredient-specific reference identified.

Formal citation: N/A

'A' number designated: N/A

## Smoke Chemistry

Brief description of reference:

Addition of eugenol to cigarettes did not increase measured smoke constituent levels and, for some constituents, reductions were reported

Formal citation:

Coggins, C.R.E., Frost-Pineda, K., Smith, D.C., Oldham, M.J., 2011

A comprehensive evaluation of the toxicology of cigarette ingredients: aromatic and aliphatic alcohol compounds. *Inhalation Toxicology*, 23 (S1), 141-156.

'A' number designated:

A0705

## Toxicological Data on Unburnt Ingredient

Brief description of reference:

The available unburnt toxicology dataset includes irritation, sensitisation, repeated-dose toxicity, genotoxicity and carcinogenicity data. A chronic dietary study in rats identified a NOAEL of 300 mg/kg bw/day, supporting the JECFA/EFSA ADI of 2.5 mg/kg bw/day.

Formal citation:

National Toxicology Program (1983). *Carcinogenesis Studies of Eugenol (CAS No. 97-53-0) in F344/N Rats and B6C3F1 Mice (Feed Studies)*. NTP Technical Report Series No. 223.

'A' number designated:

A0706

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## Transfer Studies

Brief description of reference: N/A. No ingredient-specific reference identified.

Formal citation: N/A

'A' number designated: N/A

## Addictive Properties

Brief description of reference:

No evidence was identified indicating that eugenol possesses addictive properties. Broader reviews of tobacco additives concluded that no additives had been identified as independently addictive.

Formal citation:

Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) (2010). *Addictiveness and Attractiveness of Tobacco Additives*.

'A' number designated:

A0707

## Cardiovascular Toxicity

Brief description of reference: N/A. No ingredient-specific reference identified.

Formal citation: N/A

'A' number designated: N/A

## List of Potential Sources of Reference

Below are two sections detailing potential sources of reference. The Primary Sources are those most likely to have a reference for individual ingredients for the sections above (Transfer Studies, Smoke Chemistry, etc). Other Sources are those from the standard Tox Data Repository template that *may* contain appropriate references.

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The evaluator should not limit their search to the references cited in these sections. Search engines such as [Scopus](#) (free registration required), [PubMed](#), [Embase](#) (free registration required), [ScienceDirect](#) should also be used in the absence of data from references cited herein.

Using Advanced Search options, search strings such as “Chemical Name” AND “*in vitro*” should identify any suitable references if available (variations on search strings may be needed).

If references are identified from academic search engines, search strings should be documented in the appropriate sections above, as should formal citations.

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## Primary Sources of Reference

Harm reduction in nicotine addiction, A report of the tobacco advisory group of the Royal College of Physicians, 2007.

Richard R. Baker, José R. Pereira da Silva, Graham Smith. The effect of tobacco ingredients on smoke chemistry. Part I: Flavourings and additives. Food and Chemical Toxicology, Volume 42, Supplement, 2004, Pages 3-37, ISSN 0278-6915. <https://www.sciencedirect.com/science/article/abs/pii/S0278691503001893>

Richard R. Baker, José R. Pereira da Silva, Graham Smith. The effect of tobacco ingredients on smoke chemistry. Part II: Casing ingredients. Food and Chemical Toxicology. Volume 42, Supplement, 2004, Pages 39-52. <https://www.sciencedirect.com/science/article/abs/pii/S0278691503002448>

Richard R Baker, Eian D Massey, Graham Smith. An overview of the effects of tobacco ingredients on smoke chemistry and toxicity. Food and Chemical Toxicology. Volume 42, Supplement, 2004, Pages 53-83. <https://www.sciencedirect.com/science/article/abs/pii/S0278691504000043>

Richard R Baker, Louise J Bishop. The pyrolysis of tobacco ingredients. Journal of Analytical and Applied Pyrolysis. Volume 71, Issue 1, 2004, Pages 223-311, ISSN 0165-2370. <https://www.sciencedirect.com/science/article/abs/pii/S0165237003000901>

Richard R. Baker, Louise J. Bishop. The pyrolysis of non-volatile tobacco ingredients using a system that simulates cigarette combustion conditions. Journal of Analytical and Applied Pyrolysis. Volume 74, Issues 1-2, 2005, Pages 145-170, ISSN 0165-2370. <https://www.sciencedirect.com/science/article/abs/pii/S0165237005000495>

Rodgman and Perfetti, The chemical components of tobacco and tobacco smoke, CRC Press, 2009. ISBN 978-1-4200-7883-1.

Smokeless tobacco and some tobacco-specific N-nitrosamines, IARC Monograph 89, 2007.

Tobacco smoke and involuntary smoking, IARC Monograph 83, 2004.

US Department of Health and Human Services. The Health Consequences of Smoking. Nicotine Addiction, A Report of the Surgeon General, US Government Printing Office, Washington DC, 1988.

<https://bat.sharepoint.com/:f/r/sites/GBIN-CPS900/Shared%20Documents/Tox%20Reporting/Taiwan%20Reporting?csf=1&web=1&e=GODYdm>

## Other Sources of Reference

Burdock GA (2010). Fenaroli's Handbook of Flavor Ingredients. 6th Edition. CRC Press, Boca Raton. ISBN 978-1-4200-9077-2.

California Office of Environmental Health Hazard Assessment (OEHHA) Proposition 65 list, Accessed [month-year]: <https://oehha.ca.gov/proposition-65/proposition-65-list>

European Chemicals Agency (ECHA). Accessed [month-year]: <https://echa.europa.eu/home>

European Chemicals Agency (ECHA). Authorisation List, Accessed [month-year]: <https://echa.europa.eu/authorisation-list>

European Chemicals Agency (ECHA). Candidate List of substances of very high concern (SVHC) for Authorisation, Accessed [month-year]: <https://echa.europa.eu/candidate-list-table>

European Commission list of flavourings and source materials as laid down in Part I of Annex I of Regulation (EC) No 1334/2008. Database, Accessed [month-year], available: [https://webgate.ec.europa.eu/foods\\_system/main/?event=display](https://webgate.ec.europa.eu/foods_system/main/?event=display)

European Food Safety Authority (EFSA). Accessed [month-year]: <https://www.efsa.europa.eu/en>

European Medicines Agency (EMA). Medicines Database (2022), Accessed [month-year]: <https://www.ema.europa.eu/en/medicines>

European Union Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC, Accessed [month-year]: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:32008R1334>

European Union Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, Annex II, Accessed [month-year]: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32011R1169>

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<https://bat.sharepoint.com/:f/r/sites/GBIN->

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