

## Substance Information Document

**Ethyl 2-methylbutyrate****1. Substance identity**

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| Name       | Ethyl 2-methylbutyrate   |
| Synonyms   | Butanoic acid, 2-methyl-, ethyl ester<br>Butyric acid, 2-methyl-, ethyl ester<br>Ethyl 2-methylbutanoate<br>Ethyl alpha-methylbutyrate |
| IUPAC Name | ethyl 2-methylbutanoate  |
| CAS        | 7452-79-1  |

**2. Toxicological information**

According to a RIFM Expert Panel, ethyl 2-methylbutyrate does not present a concern for genotoxicity based on current existing data. In a BlueScreen assay, ethyl 2-methylbutyrate was not cytotoxic ( $\geq 80\%$  relative cell density) to human cells.

No irritation data of the respiratory tract, skin or eye were reported.

In a combined repeated-dose toxicity and reproduction/developmental toxicity screening test conducted in accordance with OECD TG 422, no adverse effects were seen in an unspecified range of organs, but presumably including the heart and lungs, when Sprague-Dawley rats (10/sex/group) were administered ethyl 2-methyl butyrate by oral gavage at up to 1000 mg/kg bw/day for 28-51 days. Furthermore, no significant treatment-related effects on functional neurobehavior were identified.

From the available experimental data identified, ethyl 2-methylbutyrate (in non-vaporised form) is not characterized by a “known type of toxicity” and does not appear to be a substance of high concern for human health. Notably, it does not have CMR23 properties.

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| JECFA                | <a href="#">909. Esters/aliphatic acyclic prim. alcohols/branched-chain/aliphatic acyclic acids (WHO Food Additives Series 40) (inchem.org)</a>  |
| FEMA                 | <a href="#">ETHYL 2-METHYLBUTYRATE   FEMA (femaflavor.org)</a>   |
| EFSA                 | <a href="#">Safety of 31 flavouring compounds belonging to different chemical groups when used as feed additives for all animal species - - 2020 - EFSA Journal - Wiley Online Library</a> |
| ECHA – REACH dossier | <a href="#">Registration Dossier - ECHA (europa.eu)</a>  |
| PUBCHEM              | <a href="#">Ethyl 2-methylbutyrate   C7H14O2 - PubChem (nih.gov)</a>   |
| CIR                  | -  |
| OSHA                 | -  |

### 3. Addictiveness and attractiveness

No studies investigating the addictiveness of ethyl 2-methyl butyrate were identified. However, it is worth noting that no significant treatment-related effects on functional neurobehavior were identified when Sprague-Dawley rats (10/sex/group) were administered ethyl 2-methyl butyrate by oral gavage at up to 1000 mg/kg bw/day for a maximum of 51 days in a combined repeated-dose toxicity and reproduction/developmental toxicity screening test conducted in accordance with OECD TG 422.

In an investigation into the most common flavouring ingredients added to e-liquids on the Dutch market, ethyl 2-methyl butyrate (reportedly providing strong, green, fruity, apple with strawberry notes) was identified in 16% of e-liquid samples and within several flavour categories. The investigators noted that such flavourings increase e-cigarette attractiveness and use and thereby exposure to potentially toxic ingredients.

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| SCENIHR | -  |
| EMA     | -  |
| PUBMED  | <a href="#">Comprehensive overview of common e-liquid ingredients and how they can be used to predict an e-liquid's flavour category - PubMed (nih.gov)</a><br><br><a href="#">RIFM fragrance ingredient safety assessment, ethyl 2-methylbutyrate, CAS Registry Number 7452-79-1 - PubMed (nih.gov)</a> |