Substance Information Document

Furaneol

1. Substance identity

Name	Furaneol
Synonyms	2,5-Dimethyl-4-hydroxy-3(2H)-furanone (DMHF) 4-Hydroxy-2,5-dimethylfuran-3(2H)-one Alletone Dimethylhydroxy furanone Pineapple ketone
IUPAC Name	4-hydroxy-2,5-dimethylfuran-3-one
CAS	3658-77-3

2. Toxicological information

Furaneol (CAS RN 3658-77-3) is a racemic mixture of two enantiomers. No data were identified on the S- or R-forms (CAS RNs 131222-81-6 and 131222-82-7, respectively).

The REACH registrants have classified furaneol for skin corrosion and eye damage, and the identified data appear to support these classifications. No respiratory tract irritation data are available.

Furaneol was also classified by the REACH registrants as a skin allergen. RIFM recently stated that it is a moderate sensitiser with a WoE NESIL of 590 µg/cm^2. Oral furaneol has also been reported to enhance the skin and respiratory reactions of known sensitisers. Furaneol appears to be of moderate acute oral toxicity and was classified by the REACH registrants as Acute Tox. 4 by this route. No relevant acute- or repeated-dose inhalation studies were identified. A NOAEL of about 200 mg/kg bw/day was seen in a 2-year dietary rat study due to reduced growth and survival at the highest tested dose (about 400 mg/kg bw/day).

JECFA concluded that it was “highly unlikely that [furaneol]… would pose any significant genotoxic risk to humans under the conditions of use as [a food] flavouring agent”. EFSA had no concern for the potential of furaneol to induce heritable genetic damage and RIFM recently stated that it “does not present a concern for genetic toxicity”. The genotoxicity data set on furaneol is mixed, with some positive and some negative in vitro and in vivo results, but expert groups considered the lack of chromosome aberrations in male rat germ cells in a dominant lethal assay to carry the greatest weight. In this study, furaneol was unable to induce adverse effects on male rat reproductive capacity or dominant lethality following oral doses at up to 1000 mg/kg bw/day for about 13 weeks. It is also notable that no carcinogenic activity was seen in the high-quality 2-year study.

No female fertility or developmental toxicity data were identified.

No inhalation HBGVs were identified for furaneol. Based on the 2-year study, RIFM recently derived an oral RfD of 1.94 mg/kg bw/day.

JECFA	v54je01.pdf (inchem.org)

FEMA	0320 FEMA GRAS 29 (femaflavor.org)
EFSA	-
ECHA – REACH dossier	Registration Dossier - ECHA (europa.eu)
PUBCHEM	Furaneol | C6H8O3 - PubChem (nih.gov)
CIR	-
OSHA	-

3. Addictiveness and attractiveness

In an investigation into the most common flavouring ingredients added to e-liquids on the Dutch market, furaneol (reportedly providing a fruity, caramelised, roasted, pineapple-strawberry flavour) was identified in 19.3% of e-liquid samples. The investigators noted that such flavourings increase e-cigarette attractiveness and use and thereby exposure to potentially toxic ingredient.

SCENIHR	-
EMA	-
PUBMED	Comprehensive overview of common e-liquid ingredients and how they can be used to predict an e-liquid's flavour category - PubMed (nih.gov)