

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Isoeugenol Formulation

Version 2.1 Revision Date: 09.04.2021 SDS Number: 4749755-00005 Date of last issue: 23.11.2020
Date of first issue: 13.08.2019

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Isoeugenol Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification


2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Skin irritation, Category 2 H315: Causes skin irritation.
Eye irritation, Category 2 H319: Causes serious eye irritation.
Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms : 

Signal word : Warning

Hazard statements : H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.

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P280 Wear protective gloves/ eye protection/ face protection.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Hazardous components which must be listed on the label:

Isoeugenol

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Isoeugenol	97-54-1 202-590-7 604-094-00-X	Acute Tox. 4; H302 Acute Tox. 4; H312 Skin Irrit. 2; H315 Eye Irrit. 2; H319 <u>Skin Sens. 1A; H317</u> specific concentration limit Skin Sens. 1A; H317 >= 0.01 %	>= 50 - < 70

For explanation of abbreviations see section 16.

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SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.
- In case of skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : Causes skin irritation.
May cause an allergic skin reaction.
Causes serious eye irritation.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.
-

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.

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5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not get on skin or clothing.
Avoid breathing vapours.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.
- Advice on common storage : Do not store with the following product types:
Strong oxidizing agents

7.3 Specific end use(s)

- Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Isoeugenol	97-54-1	TWA	OEB 3 ($\geq 10 < 100$ $\mu\text{g}/\text{m}^3$)	Internal
Further information: DSEN				

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8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Laboratory operations do not require special containment.

Personal protective equipment

- | | | |
|-----------------------------|---|--|
| Eye protection | : | Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. |
| Hand protection
Material | : | Chemical-resistant gloves |
| Skin and body protection | : | Work uniform or laboratory coat. |
| Respiratory protection | : | No personal respiratory protective equipment normally required. |
-

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- | | | |
|--|---|-------------------|
| Physical state | : | viscous liquid |
| Colour | : | yellow |
| Odour | : | floral |
| Odour Threshold | : | No data available |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | 266 °C |
| Flammability (solid, gas) | : | Not applicable |
| Flammability (liquids) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Flash point | : | No data available |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature
Decomposition temperature | : | No data available |
| pH | : | No data available |

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Viscosity
Viscosity, kinematic : No data available

Solubility(ies)
Water solubility : dispersible
Solubility in other solvents : soluble
Solvent: Ethanol

Partition coefficient: n-octanol/water : Not applicable
Vapour pressure : < 0.02 mmHg (25 °C)

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Particle characteristics
Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:

Isoeugenol:

Acute oral toxicity : LD50 (Rat): 1,290 mg/kg

Acute dermal toxicity : LD50 (Rabbit): 1,912 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Components:

Isoeugenol:

Species : Rabbit
Result : Skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Isoeugenol:

Result : Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

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Components:

Isoeugenol:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Humans
Method : OECD Test Guideline 406
Result : positive

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : positive

Assessment : Probability or evidence of high skin sensitisation rate in humans

Germ cell mutagenicity

Not classified based on available information.

Components:

Isoeugenol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:

Isoeugenol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

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STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Isoeugenol:

Species : Rat
NOAEL : 75 mg/kg
LOAEL : 150 mg/kg
Application Route : Ingestion
Exposure time : 14 Weeks

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 12: Ecological information

12.1 Toxicity

Components:

Isoeugenol:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 7.5 mg/l
Exposure time: 48 h

12.2 Persistence and degradability

Components:

Isoeugenol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 79 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

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12.3 Bioaccumulative potential

Components:

Isoeugenol:

Partition coefficient: n-octanol/water : log Pow: 3.04

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

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14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)	:	Conditions of restriction for the following entries should be considered: Number on list 3
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	:	Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	:	Not applicable
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.	:	Not applicable

Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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Full text of H-Statements

H302 : Harmful if swallowed.
H312 : Harmful in contact with skin.
H315 : Causes skin irritation.
H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Eye Irrit. : Eye irritation
Skin Irrit. : Skin irritation
Skin Sens. : Skin sensitisation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Classification of the mixture:

Classification procedure:

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Skin Irrit. 2	H315	Calculation method
Eye Irrit. 2	H319	Calculation method
Skin Sens. 1	H317	Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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