SAFETY DATA SHEET

Clanobutin Formulation

Version 1.3  Revision Date: 09/13/2019  SDS Number: 3667472-00004  Date of last issue: 04/24/2019
Date of first issue: 11/09/2018

SECTION 1. IDENTIFICATION

Product name: Clanobutin Formulation

Manufacturer or supplier’s details
Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200
Skin irritation: Category 2
Eye irritation: Category 2B

GHS label elements
Hazard pictograms: ✔

Signal Word: Warning
Hazard Statements: H315 + H320 Causes skin and eye irritation.
Precautionary Statements: Prevention:
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332 + P313 If skin irritation 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.

Other hazards
None known.
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Clanobutin</td>
<td>30544-61-7</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

SECTION 4. 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.
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.
Most important symptoms and effects, both acute and delayed : Causes skin and eye irritation.
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).
Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
                               Alcohol-resistant foam
                               Carbon dioxide (CO2)
                               Dry chemical
Unsuitable extinguishing media : None known.
Specific hazards during firefighting : Vapors may form explosive mixtures with air.
                                      Exposure to combustion products may be a hazard to health.
Hazardous combustion products : Carbon oxides
                                 Nitrogen oxides (NOx)
Specific extinguishing method : Use extinguishing measures that are appropriate to local cir-
Emergency procedures:
Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions:
Discharge into the environment must be avoided. 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.

Methods and materials for containment and cleaning up:
Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 7. HANDLING AND STORAGE

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 inhalation of vapor or mist. Do not swallow. Do not get in eyes. 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.

Conditions for safe storage:
Keep in properly labeled containers. Store in accordance with the particular national regulations.

Materials to avoid:
Do not store with the following product types: Strong oxidizing agents.
SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clanobutin</td>
<td>30544-61-7</td>
<td>TWA</td>
<td>0.3 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

**Engineering measures**: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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**

**Respiratory protection**: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**Hand protection**

**Material**: Chemical-resistant gloves

**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.

**Skin and body protection**

**Hygiene measures**: Work uniform or laboratory coat. 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. 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.
## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
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<tr>
<td>Color</td>
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<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
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</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
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<td>Initial boiling point and boiling</td>
<td>No data available</td>
</tr>
<tr>
<td>range</td>
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<tr>
<td>Flash point</td>
<td>200.1 °F / 93.4 °C</td>
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<tr>
<td>Evaporation rate</td>
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</tr>
<tr>
<td>Flammability (solid, gas)</td>
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</tr>
<tr>
<td>Flammability (liquids)</td>
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<td>Upper explosion limit / Upper</td>
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</tr>
<tr>
<td>flammability limit</td>
<td></td>
</tr>
<tr>
<td>Lower explosion limit / Lower</td>
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</tr>
<tr>
<td>flammability limit</td>
<td></td>
</tr>
<tr>
<td>Vapor pressure</td>
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</tr>
<tr>
<td>Relative vapor density</td>
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</tr>
<tr>
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</tr>
<tr>
<td>Density</td>
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<tr>
<td>Solubility(ies)</td>
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<tr>
<td>Water solubility</td>
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<td>Partition coefficient: n-octanol/water</td>
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<td>Autoignition temperature</td>
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</tr>
<tr>
<td>Decomposition temperature</td>
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</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
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</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
</tbody>
</table>
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Oxidizing properties: The substance or mixture is not classified as oxidizing.

Molecular weight: No data available

Particle size: Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Vapors may form explosive mixture with air.
Can react with strong oxidizing agents.

Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

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: > 5,000 mg/kg
Method: Calculation method

Components:

Clanobutin:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Acute toxicity (other routes of administration): LD50 (Rat): 570 mg/kg
Application Route: Intravenous

Skin corrosion/irritation
Causes skin irritation.

Components:

Clanobutin:
Result: irritating

Serious eye damage/eye irritation
Causes eye irritation.
Components:

Clanobutin:
Result : Severe irritation

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Carcinogenicity
Not classified based on available information.
IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
Not classified based on available information.

Components:

Clanobutin:
Effects on fetal development : Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 250 mg/kg body weight

Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 250 mg/kg body weight

STOT-single exposure
Not classified based on available information.

Components:

Clanobutin:
Routes of exposure : Inhalation
Assessment : May cause respiratory irritation.

STOT-repeated exposure
Not classified based on available information.
Repeated dose toxicity

**Components:**

**Clanobutin:**
- Species: Dog
- LOAEL: 500 mg/kg
- Application Route: Oral
- Exposure time: 4 Weeks
- Target Organs: Central nervous system
- Symptoms: Tremors, Disorientation

- Species: Rat
- NOAEL: 300 mg/kg
- LOAEL: 500 mg/kg
- Application Route: Oral
- Exposure time: 6 Months
- Target Organs: Kidney, Liver, Thyroid

- Species: Dog
- NOAEL: 300 mg/kg
- LOAEL: 600 mg/kg
- Application Route: Oral
- Exposure time: 6 Months
- Target Organs: Kidney, Liver, Thyroid

**Aspiration toxicity**
Not classified based on available information.

**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Clanobutin:**

**Ecotoxicology Assessment**
- Acute aquatic toxicity: Toxic effects cannot be excluded
- Chronic aquatic toxicity: Toxic effects cannot be excluded

**Persistence and degradability**
No data available

**Bioaccumulative potential**
No data available

**Mobility in soil**
No data available

**Other adverse effects**
No data available
SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods:
- Waste from residues: Dispose of in accordance with local regulations.
- 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

International Regulations:
- UNRTDG: Not regulated as a dangerous good
- IATA-DGR: Not regulated as a dangerous good
- IMDG-Code: Not regulated as a dangerous good
- Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:
  Not applicable for product as supplied.

Domestic regulation:
- 49 CFR: Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity:
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity:
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity:
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards:
- Skin corrosion or irritation
- Serious eye damage or eye irritation

SARA 313:
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations:

Pennsylvania Right To Know:
- Water: 7732-18-5
- Clanobutin: 30544-61-7

The ingredients of this product are reported in the following inventories:
SECTION 16. OTHER INFORMATION

Further information

**NFPA 704:**

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Health</th>
<th>Instability</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>

**HMIS® IV:**

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>FLAMMABILITY</th>
<th>PHYSICAL HAZARD</th>
</tr>
</thead>
<tbody>
<tr>
<td>/</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The """" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); EfCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; KECl - 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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 sub-
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Version: 1.3
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Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 09/13/2019

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.

US / Z8