SECTION 1. IDENTIFICATION

Product name: Febantel / Pyrantel Pamoate / Praziquantel Formulation
Other means of identification: No data available

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 the Hazardous Products Regulations
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
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<tr>
<td>Cellulose</td>
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<tr>
<td>Febantel</td>
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<td>&gt;= 10 - &lt; 30</td>
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<tr>
<td>4,4'-Methylenebis[3-hydroxy-2-</td>
<td>22204-24-6</td>
<td>&gt;= 10 - &lt; 30</td>
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<tr>
<td>naphthoic] acid, compound with</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1)</td>
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<tr>
<td>Praziquantel</td>
<td>55268-74-1</td>
<td>&gt;= 5 - &lt; 10</td>
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<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 5 - &lt; 10</td>
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</table>

Actual concentration or concentration range 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
If inhaled: If inhaled, remove to fresh air. Get medical attention if symptoms occur.
In case of skin contact: Wash with water and soap. Get medical attention if symptoms occur.
In case of eye contact: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.
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:
Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical 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:
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
Carbon oxides
Nitrogen oxides (NOx)
Sulfur oxides

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.

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. 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:
- Sweep up or vacuum up spillage and collect in a suitable container for disposal.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
- Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- 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:
- Static electricity may accumulate and ignite suspended dust causing an explosion.
- Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation:
- Use only with adequate ventilation.

Advice on safe handling:
- Do not breathe dust.
- Do not swallow.
- Avoid contact with eyes.
- Avoid prolonged or repeated contact with skin.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- 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>
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<tr>
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<td>CA AB OEL</td>
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SAFETY DATA SHEET

Febantel / Pyrantel Pamoate / Praziquantel
Formulation

<table>
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<th>10 mg/m³</th>
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Engineering measures: All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Particulates type

Hand protection: Chemical-resistant gloves

Remarks: Consider double gloving.

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: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets,
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.
- 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

- Appearance: powder
- Color: yellow
- Odor: No data available
- Odor Threshold: No data available
- pH: No data available
- Melting point/freezing point: No data available
- Initial boiling point and boiling range: No data available
- Flash point: Not applicable
- Evaporation rate: Not applicable
- Flammability (solid, gas): May form explosive dust-air mixture during processing,
handling or other means.
- Flammability (liquids): No data available
- Upper explosion limit / Upper flammability limit: No data available
- Lower explosion limit / Lower flammability limit: No data available
- Vapor pressure: Not applicable
- Relative vapor density: Not applicable
- Relative density: No data available
- Density: No data available
- Solubility(ies):
SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

Conditions to avoid: Heat, flames and sparks. Avoid dust formation.
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: 4,708 mg/kg
Method: Calculation method

Components:
Cellulose:
SAFETY DATA SHEET

Febantel / Pyrantel Pamoate / Praziquantel Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
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<td>1.2</td>
<td>09/13/2019</td>
<td>3771246-00003</td>
<td>04/24/2019</td>
<td>11/19/2018</td>
</tr>
</tbody>
</table>

Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 5.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

**Febantel:**

Acute oral toxicity: LD50 (Rabbit): 1,250 mg/kg

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

4,4′-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

Acute oral toxicity: LD50 (Rat): > 24,000 mg/kg
LD50 (Mouse): > 24,000 mg/kg
LD50 (Dog): 2,000 mg/kg

**Praziquantel:**

Acute oral toxicity: LD50 (Rat): 2,480 mg/kg
LD50 (Mouse): 2,454 mg/kg
LD50 (Dog): > 200 mg/kg
LD50 (Rabbit): 1,050 mg/kg

**Starch:**

Acute oral toxicity: LD50 (Mouse): > 5,000 mg/kg

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

**Febantel:**

Species: Rabbit
Result: No skin irritation

**Praziquantel:**

Species: Rabbit
Method: Draize Test
Remarks: slight irritation

**Serious eye damage/eye irritation**
Not classified based on available information.
Components:

Febantel:
Species: Rabbit
Result: No eye irritation

Praziquantel:
Species: Rabbit
Result: Mild eye irritation
Method: Draize Test

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Praziquantel:
Test Type: Maximization Test
Routes of exposure: Dermal
Species: Guinea pig
Result: Not a skin sensitizer.

Germ cell mutagenicity
Not classified based on available information.

Components:

Cellulose:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: In vitro mammalian cell gene mutation test
  Result: negative

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

Febantel:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
  Result: negative
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

4,4’-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

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

Test Type: Chromosomal aberration
Test system: Chinese hamster cells
Result: negative

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Rat
Result: negative

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Cellulose:**
Species: Rat
Application Route: Ingestion
Exposure time: 72 weeks
Result: negative

**Febantel:**
Species: Mouse
Application Route: Ingestion
Exposure time: 21 Months
Result: negative

**Praziquantel:**
Species: Hamster
Application Route: Oral
Exposure time: 80 weeks
NOAEL: 100 mg/kg body weight
Result: negative
Remarks: No significant adverse effects were reported
Species: Rat
Application Route: Oral
Exposure time: 104 weeks
NOAEL: 250 mg/kg body weight
Result: negative
Remarks: No significant adverse effects were reported

Reproductive toxicity
Not classified based on available information.

Components:

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

Effects on fetal development: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

Febantel:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative

Effects on fetal development: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative

4,4’-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):
Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 3,000 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 1,000 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.
Praziquantel:
Effects on fertility: Test Type: Fertility
Species: Rat
Remarks: No significant adverse effects were reported

Effects on fetal development: Test Type: Development
Species: Rat
Remarks: No significant adverse effects were reported

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Cellulose:
Species: Rat
NOAEL: >= 9,000 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

4,4’-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):
Species: Dog
NOAEL: 10 mg/kg
LOAEL: 30 mg/kg
Application Route: Ingestion
Exposure time: 3 d
Remarks: No significant adverse effects were reported

Species: Dog
NOAEL: 600 mg/kg
Application Route: Oral
Exposure time: 19 d
Remarks: No significant adverse effects were reported

Species: Dog
NOAEL: 600 mg/kg
Application Route: Oral
Exposure time: 30 d
Remarks: No significant adverse effects were reported
SAFETY DATA SHEET

Febantel / Pyrantel Pamoate / Praziquantel Formulation

Version 1.2  Revision Date: 09/13/2019  SDS Number: 3771246-00003  Date of last issue: 04/24/2019
Date of first issue: 11/19/2018

Species: Dog  NOAEL: 600 mg/kg  Application Route: Oral  Exposure time: 90 d  Remarks: No significant adverse effects were reported

Praziquantel:
Species: Rat  NOAEL: 1,000 mg/kg  Application Route: Oral  Exposure time: 4 weeks  Remarks: No significant adverse effects were reported

Species: Dog  NOAEL: 180 mg/kg  Application Route: Oral  Exposure time: 13 weeks  Remarks: No significant adverse effects were reported

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):
Ingestion: Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhea, Headache, Dizziness, Fever

Praziquantel:
Inhalation: Symptoms: Headache, Tiredness, Dizziness, Gastrointestinal discomfort, decrease body temperature, Allergic reactions

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:
Toxicity to fish: LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l  Exposure time: 48 h  Remarks: Based on data from similar materials

Febantel:
Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 100 mg/l  Exposure time: 96 h

Toxicity to daphnia and other: EC50 (Daphnia magna (Water flea)): 0.2 mg/l
SAFETY DATA SHEET

Febantel / Pyrantel Pamoate / Praziquantel Formulation

aquatic invertebrates

Exposure time: 48 h

Toxicity to algae/aquatic plants

: ErC50 (Desmodesmus subspicatus (green algae)): > 0.43 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

: NOEC (Daphnia magna (Water flea)): > 0.001 - 0.01 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: Based on data from similar materials

4,4’-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

Ecotoxicology Assessment

Acute aquatic toxicity

: Toxic effects cannot be excluded

Chronic aquatic toxicity

: Toxic effects cannot be excluded

Praziquantel:

Toxicity to fish

: LC50 (Carassius auratus (goldfish)): 29.2 mg/l
Exposure time: 96 hrs
Method: OECD Test Guideline 203

Persistence and degradability

Components:

Cellulose:

Biodegradability

: Result: Readily biodegradable.

Bioaccumulative potential

Components:

Febantel:

Partition coefficient: n-octanol/water

: log Pow: 1.95
Remarks: Calculation

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
SECTION 14. TRANSPORT INFORMATION

International Regulations

**UNRTDG**

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**IATA-DGR**

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**IMDG-Code**

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<td>EmS Code</td>
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<td>Marine pollutant</td>
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**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Domestic regulation**

**TDG**

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</tr>
<tr>
<td>Marine pollutant</td>
<td>yes (Febantel)</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Febantel / Pyrantel Pamoate / Praziquantel Formulation

Version 1.2 Revision Date: 09/13/2019 SDS Number: 3771246-00003 Date of last issue: 04/24/2019 Date of first issue: 11/19/2018

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL: Canada. British Columbia OEL
CA QC OEL: Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA: 8-hour, time-weighted average
CA AB OEL / TWA: 8-hour Occupational exposure limit
CA BC OEL / TWA: 8-hour time weighted average
CA QC OEL / TWA EV: Time-weighted average exposure value

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Civil Aviation Organization; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Air Transport Association; 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Develop-
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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.

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