

# SAFETY DATA SHEET

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## SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/ UNDERTAKING

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### Contact information

#### General



Celgene Corporation  
86 Morris Avenue, Summit, NJ 07901  
Main: +1 (908) 673-9000  
E-mail: MSDScoordinator@Celgene.com

#### Emergency telephone number

Chemtrec (24-hour availability):  
+1 (800) 424-9300 (USA and Canada)  
+1 (703) 527-3887 (International; collect calls accepted)

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<b>Product identifier</b>	Revlimid® (Lenalidomide) Capsules (2.5, 5, 10, 15, 20 and 25 mg)
<b>Synonyms</b>	None identified
<b>Trade names</b>	Revlimid®
<b>Chemical family</b>	Piperidinedione (lenalidomide)
<b>Relevant identified uses of the substance or mixture and uses advised against</b>	Bulk formulated pharmaceutical product/ Formulated pharmaceutical product packaged in final form for patient use
<b>Note</b>	The physical, chemical and ecological properties of this material and/or its ingredients have not been fully characterized. This SDS will be revisited as more data become available.

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## SECTION 2 - HAZARDS IDENTIFICATION

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<b>Classification of the substance or mixture</b>	<b>Drugs in the finished state and intended for the final user are not subject to labeling in the US, EU or Canada.</b> Please consult the prescribing/packaging information. <b>The classification and labelling listed below is for bulk Revlimid Capsules.</b>
<b>Globally Harmonized System [GHS]</b>	Specific Target Organ Toxicity (repeated exposure) - Category 1. Reproductive Toxicity - Category 1B. Carcinogenic - Category 2.

### Label elements

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**SECTION 2 - HAZARDS IDENTIFICATION ...continued**

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**GHS hazard pictogram****GHS signal word**

Danger

**GHS hazard statements**

H360D - May damage the unborn child. H372 - Causes damage to hematopoietic system through prolonged or repeated exposure. H351 - Suspected of causing cancer.

**GHS precautionary statements**

P201 - Obtain special instructions before use. P260 - Do not breathe dust. P264 - Wash hands thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P281 - Use personal protective equipment as required. P308 + P313 - If exposed or concerned: get medical advice/attention. P405 - Store locked up. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

**Other hazards**

Severe hematological toxicity (including neutropenia and thrombocytopenia) occurs in patients taking 10 mg/day. The other most commonly observed adverse events associated with therapeutic use of lenalidomide include gastrointestinal disturbances, increased tendency for infections, vascular disorders (including potentially dangerous blood clots), itchiness, rash, anemia and fatigue.

No human studies of pregnancy outcomes after exposure to lenalidomide have been conducted. However, because it is an analog of thalidomide (a known human teratogen) and is teratogenic in monkeys at low doses, lenalidomide is considered a probable human developmental toxicant.

There is an increased risk of second primary malignancies (SPMs) in certain cancer patients treated with lenalidomide in combination with other chemotherapeutics as observed in clinical trials. Although some were determined to be associated with the initial drug treatment, the cancer risk of lenalidomide cannot be completely ruled out.

**Note**

This mixture is classified as hazardous under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA).

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**SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS**

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<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ ELINCS#</u>	<u>Amount</u>	<u>GHS Classification</u>
Cellulose	9004-34-6	232-674-9	20-40%	Not classified
Lenalidomide	191732-72-6	N/A	2.50- 6.25%	STOT-R1: H372; RT1B: H360D; Carc2: H351
Magnesium Stearate	557-04-0	209-150-3	0.75- 1.0%	Not classified

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**SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS ...continued**

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**Note** The ingredient(s) listed above are considered hazardous. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of GHS classifications. Cellulose and magnesium stearate are included because they have OELs.

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**SECTION 4 - FIRST AID MEASURES**

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**Description of first aid measures**

<b>Immediate Medical Attention Needed</b>	Yes
<b>Eye Contact</b>	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Skin Contact</b>	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Inhalation</b>	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
<b>Ingestion</b>	Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
<b>Protection of first aid responders</b>	See Section 8 for Exposure Controls/Personal Protection recommendations.
<b>Most important symptoms and effects, both acute and delayed</b>	See Sections 2 and 11
<b>Indication of immediate medical attention and special treatment needed, if necessary</b>	Treat symptomatically and supportively. If accidental exposure occurs to an individual who is also taking one or more concomitant medications, consult the respective package or prescribing information for potential drug interactions.

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**SECTION 5 - FIREFIGHTING MEASURES**

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<b>Extinguishing media</b>	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
<b>Specific hazards arising from the substance or mixture</b>	No information identified. May emit toxic fumes of carbon monoxide, carbon dioxide, and oxides of nitrogen.
<b>Flammability/Explosivity</b>	Not considered to be a fire hazard. No explosivity data available. High concentrations of finely divided airborne organic particles can potentially explode if ignited.

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## SECTION 5 - FIREFIGHTING MEASURES...continued

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**Advice for firefighters**      Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

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## SECTION 6 - ACCIDENTAL RELEASE MEASURES

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**Personal precautions, protective equipment and emergency procedures**      If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. Do not breathe dust.

**Environmental precautions**      Do not empty into drains. Avoid release to the environment.

**Methods and material for containment and cleaning up**      If capsules are broken or crushed, DO NOT RAISE DUST. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container suitable for disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice.

**Reference to other sections**      See Sections 8 and 13 for more information.

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## SECTION 7 - HANDLING AND STORAGE

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**Precautions for safe handling**      If capsules are crushed or broken, dust containing drug substance may be released. Minimize dust generation and accumulation. Follow recommendations for handling bulk formulated/packaged pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Wash thoroughly after handling. Avoid breathing dust. Wash thoroughly after handling.

**Conditions for safe storage including any incompatibilities**      Store at room temperature away from incompatible materials. Keep out of reach of children. Avoid extreme temperatures. Store locked up.

**Specific end use(s)**      No information identified.

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## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

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**Note**      *\*Controlling to the OEL (see below) should protect workers against all potential hazards (including developmental effects and potential carcinogenicity).*

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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION...continued**


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**Control Parameters/  
Occupational Exposure  
Limit Values**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Cellulose	ACGIH, Australia, Belgium, Estonia, France, Portugal, Romania, Singapore, Spain	TWA-8 HR	10 mg/m <sup>3</sup>
	Ireland, United Kingdom	TWA-8 HR	10 mg/m <sup>3</sup> (inhalable dust); 4 mg/m <sup>3</sup> (respirable dust)
	Ireland	STEL	20 mg/m <sup>3</sup> (total inhalable dust)
	Latvia	TWA-8 HR	2 mg/m <sup>3</sup>
	Mexico	TWA-8 HR/STEL	10/20 mg/m <sup>3</sup>
	NIOSH	TWA-8 HR	10 mg/m <sup>3</sup> (total dust); 5 mg/m <sup>3</sup> (respirable dust)
	OSHA	TWA-8 HR	15 mg/m <sup>3</sup> (total dust); 5 mg/m <sup>3</sup> (respirable fraction)
	United Kingdom	STEL	20 mg/m <sup>3</sup> (inhalable dust); 12 mg/m <sup>3</sup> (respirable dust)
Lenalidomide	Celgene	TWA-8 HR	3 µg/m <sup>3</sup> *
Magnesium Stearate	ACGIH	TWA-8 HR	10 mg/m <sup>3</sup> (stearates)
	Lithuania	TWA-8 HR	3 mg/m <sup>3</sup>
	Sweden	TWA-8 HR	5 mg/m <sup>3</sup>

**Exposure/Engineering  
controls**

None required for normal handling of packaged product. If handling bulk capsules or capsules are crushed or broken: Control exposures to below the OEL (if available). Otherwise, selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Open handling should not be performed when handling potent substances, or substances of unknown toxicity. Material should be handled inside a closed process, ventilated enclosure, isolator or device of equivalent or better control that is suitable for dusts and/or aerosols.

**Respiratory  
protection**

None required for normal handling of packaged product. If handling bulk capsules or capsules are crushed or broken: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine powder handling tasks, an approved and properly worn powered air-purifying respirator equipped with HEPA filters or combination filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a positive-pressure air-supplied respirator if there is any

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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION...continued**

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<b>Respiratory protection</b> ...continued	potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where air purifying respirators may not provide adequate protection.
<b>Hand protection</b>	Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
<b>Skin protection</b>	Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.
<b>Eye/face protection</b>	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
<b>Environmental Exposure Controls</b>	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
<b>Other protective measures</b>	Wash hands in the event of contact with this substance, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

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**Information on basic physical and chemical properties**

<b>Appearance</b>	Capsules; All imprinted with "REV" on one half and dosage in "mg" on the other half in black ink.
<b>Color</b>	2.5-mg (white and blue-green opaque); 5-mg (white opaque); 10-mg (blue/green and pale yellow opaque); 15-mg (powder blue and white opaque); 20-mg (powder blue and blue-green opaque); and, 25-mg (white opaque)
<b>Odor</b>	No information identified.
<b>Odor threshold</b>	No information identified.
<b>pH</b>	No information identified.
<b>Melting point/ freezing point</b>	265-270°C (lenalidomide)
<b>Initial boiling point and boiling range</b>	No information identified.

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued**

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<b>Flash point</b>	No information identified.
<b>Evaporation rate</b>	No information identified.
<b>Flammability (solid, gas)</b>	No information identified.
<b>Upper/lower flammability or explosive limits</b>	No information identified.
<b>Vapor pressure</b>	No information identified.
<b>Vapor density</b>	No information identified.
<b>Relative density</b>	No information identified.
<b>Water solubility</b>	<1.5 mg/L (lenalidomide)
<b>Solvent solubility</b>	No information identified.
<b>Partition coefficient (n-octanol/water)</b>	No information identified.
<b>Auto-ignition temperature</b>	No information identified.
<b>Decomposition temperature</b>	No information identified.
<b>Viscosity</b>	No information identified.
<b>Explosive properties</b>	No information identified.
<b>Oxidizing properties</b>	No information identified.
<b>Other information</b>	
<b>Molecular formula</b>	C <sub>13</sub> H <sub>13</sub> N <sub>3</sub> O <sub>3</sub> (lenalidomide)
<b>Molecular weight</b>	259.25 (lenalidomide)

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**SECTION 10 - STABILITY AND REACTIVITY**

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<b>Reactivity</b>	No information identified.
<b>Chemical stability</b>	Chemically stable; pharmacological stability not guaranteed beyond expiration date imprinted on package.
<b>Possibility of hazardous reactions</b>	Not expected to occur.
<b>Conditions to avoid</b>	Avoid extreme temperatures.
<b>Incompatible materials</b>	Strong oxidizers.
<b>Hazardous decomposition products</b>	No information identified.





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**SECTION 11 - TOXICOLOGICAL INFORMATION ...continued**

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**Genotoxicity** Negative in the Ames bacterial mutagenicity assay, a mutagenicity assay in mouse lymphoma cells, a clastogenicity assay in cultured human lymphocytes, a Syrian hamster embryo transformation assay and the *in vivo* rat micronucleus assay.

**Carcinogenicity** No long-term cancer studies were identified for lenalidomide. However, no neoplastic or pre-neoplastic changes were observed at necropsy in the 26- and 52-week repeat oral dose studies in rats (up to 300 mg/kg/day) and monkeys (up to 2 mg/kg/day), respectively. This substance is not listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

**Aspiration hazard** No data available.

**Human health data** Severe hematological toxicity (including neutropenia and thrombocytopenia) occurs in patients taking 10 mg/day. The other most commonly observed adverse events associated with therapeutic use of lenalidomide include gastrointestinal disturbances, increased tendency for infections, vascular disorders (including potentially dangerous blood clots), itchiness, rash, anemia and fatigue.

No human studies of pregnancy outcomes after exposure to lenalidomide have been conducted. However, because it is an analog of thalidomide (a known human teratogen) and is teratogenic in monkeys at low doses, lenalidomide is considered a probable human developmental toxicant.

There is an increased risk of second primary malignancies (SPMs) in certain cancer patients treated with lenalidomide in combination with other chemotherapeutics as observed in clinical trials. Although some were determined to be associated with the initial drug treatment, the cancer risk of lenalidomide cannot be completely ruled out.

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**SECTION 12 - ECOLOGICAL INFORMATION**

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**Toxicity**

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Cellulose	--	--	--
Lenalidomide	--	--	--
Magnesium Stearate	--	--	--

**Persistence and Degradability** No data available.

**Bioaccumulative potential** No data available.

**Mobility in soil** No data available.

**Results of PBT and vPvB assessment** Not performed.

**Other adverse effects** No data available.

**Note** The environmental characteristics of the formulated product have not been fully investigated. Releases to the environment should be avoided.

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## SECTION 13 - DISPOSAL CONSIDERATIONS

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**Waste treatment methods** Dispose of wastes by appropriately permitted chemical waste incinerator in accordance to prescribed federal, state, and local guidelines. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, *e.g.*, appropriately permitted municipal or onsite wastewater treatment facility.

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## SECTION 14 - TRANSPORT INFORMATION

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**Transport** This product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.

**UN number** None assigned.

**UN proper shipping name** None assigned.

**Transport hazard classes and packing group** None assigned.

**Environmental hazards** Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.

**Special precautions for users** Due to lack of data, avoid release to the environment.

**Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

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## SECTION 15 - REGULATORY INFORMATION

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**Safety, health and environmental regulations/legislation specific for the substance or mixture** This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.

**Chemical safety assessment** Not conducted.

**TSCA status** Not listed

**SARA section 313** Not listed.

**California proposition 65** Not listed.

**Additional information** No other information identified.

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## SECTION 16 - OTHER INFORMATION

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**Full text of H phrases and GHS classifications** STOT-R1 - Specific Target Organ Toxicity Following Repeated Exposure Category 1. H372 - Causes damage to hematopoietic system through prolonged or repeated exposure. RT1B - Reproductive toxicity Category 1B. H360D - May damage the unborn child. Carc2 - Carcinogenicity Category 2. H351 - Suspected of causing cancer.

**Sources of data** Information from published literature and internal company data.

**Abbreviations** ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PBT - Persistent, Bioaccumulative, and Toxic; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

**Issue Date** 21 May 2019

**Revisions** Reviewed new internal data (no changes necessary); Updated address in Section 1.

**Disclaimer** The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions.

No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a potent pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.