

## Vitamin B Formulation

Version 6.0      Revision Date: 12/13/2025      SDS Number: 292427-00025      Date of last issue: 12/06/2025  
Date of first issue: 10/02/2015

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### SECTION 1. IDENTIFICATION

Product name : Vitamin B Formulation  
Other means of identification : No data available

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical  
Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Serious eye damage : Category 1

#### GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H318 Causes serious eye damage.

Precautionary Statements : **Prevention:**  
P280 Wear eye protection and face protection.

**Response:**  
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER.

#### Other hazards

None known.

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### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

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# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Vitamin B Formulation

Version 6.0      Revision Date: 12/13/2025      SDS Number: 292427-00025      Date of last issue: 12/06/2025  
Date of first issue: 10/02/2015

### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Nicotinamide	3-Pyridinecarboxamide	98-92-0	$\geq 5 - < 10$ *
Pyridoxine Hydrochloride	3,4-Pyridinedimethanol, 5-hydroxy-6-methyl-, hydrochloride	58-56-0	$\geq 1 - < 5$ *
Thiamine hydrochloride	No data available	67-03-8	$\geq 1 - < 5$ *

\* 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 advice.
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.
- In case of skin contact : Wash with water and soap as a precaution.  
Get medical attention if symptoms occur.
- 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 immediately.
- 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 serious eye damage.  
No information available.
- 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 (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire : Exposure to combustion products may be a hazard to health.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Vitamin B Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/06/2025
6.0	12/13/2025	292427-00025	Date of first issue: 10/02/2015

---

fighting

Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Chlorine compounds  
Oxides of phosphorus  
Metal 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.

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

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

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.

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.

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### SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.  
Local/Total ventilation : Use only with adequate ventilation.

---

## Vitamin B Formulation

Version 6.0      Revision Date: 12/13/2025      SDS Number: 292427-00025      Date of last issue: 12/06/2025  
Date of first issue: 10/02/2015

- Advice on safe handling : Avoid inhalation of vapor or mist.  
Do not swallow.  
Do not get in 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  
Keep container tightly closed.  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.  
Keep tightly closed.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Pyridoxine Hydrochloride	58-56-0	TWA	OEB 3 ( $\geq 10 < 100 \mu\text{g}/\text{m}^3$ )	Internal
Thiamine hydrochloride	67-03-8	TWA	OEB 1 ( $\geq 1000 \mu\text{g}/\text{m}^3$ )	Internal

- Engineering measures** : Ensure adequate ventilation, especially in confined areas.  
Minimize workplace exposure concentrations.

#### 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
- Material : Chemical-resistant gloves
- Remarks : Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often!  
For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
- Eye protection : Wear the following personal protective equipment:  
Chemical resistant goggles must be worn.  
If splashes are likely to occur, wear:  
Face-shield
- Skin and body protection : Select appropriate protective clothing based on chemical

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Vitamin B Formulation

Version 6.0      Revision Date: 12/13/2025      SDS Number: 292427-00025      Date of last issue: 12/06/2025  
Date of first issue: 10/02/2015

---

Hygiene measures : resistance data and an assessment of the local exposure potential.  
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).  
: 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.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : No data available

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 : No data available

Evaporation rate : No data available

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

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Vitamin B Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/06/2025
6.0	12/13/2025	292427-00025	Date of first issue: 10/02/2015

---

Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics		
Particle size	:	No data available

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

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### 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: > 2,000 mg/kg Method: Calculation method
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#### Components:

##### Nicotinamide:

Acute oral toxicity	:	LD50 (Rat): > 2,500 mg/kg Method: OECD Test Guideline 423 Assessment: The substance or mixture has no acute oral tox-
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# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Vitamin B Formulation

Version 6.0      Revision Date: 12/13/2025      SDS Number: 292427-00025      Date of last issue: 12/06/2025  
Date of first issue: 10/02/2015

---

icity

Acute inhalation toxicity : LC50 (Rat): > 3.8 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 436  
Assessment: The substance or mixture has no acute inhalation toxicity  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity

### **Pyridoxine Hydrochloride:**

Acute oral toxicity : LD50 (Rat): 4,000 mg/kg

### **Thiamine hydrochloride:**

Acute oral toxicity : LD50 (Rat): 3,710 mg/kg  
Target Organs: Central nervous system, Lungs  
  
LD50 (Mouse): 8,224 mg/kg

### **Skin corrosion/irritation**

Not classified based on available information.

### **Components:**

#### **Nicotinamide:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

#### **Pyridoxine Hydrochloride:**

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 439  
Remarks : The test was conducted according to guideline  
  
Result : No skin irritation

### **Serious eye damage/eye irritation**

Causes serious eye damage.

### **Components:**

#### **Nicotinamide:**

Species : Rabbit  
Result : Irritation to eyes, reversing within 7 days  
Method : OECD Test Guideline 405

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Vitamin B Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/06/2025
6.0	12/13/2025	292427-00025	Date of first issue: 10/02/2015

---

### Pyridoxine Hydrochloride:

Species : Bovine cornea  
Method : OECD Test Guideline 437  
Remarks : The test was conducted according to guideline

Result : Irreversible effects on the eye

### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

### Components:

#### Nicotinamide:

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

#### Pyridoxine Hydrochloride:

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : The test was conducted according to guideline

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Nicotinamide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Method: OECD Test Guideline 474  
Result: negative

#### Pyridoxine Hydrochloride:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Vitamin B Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/06/2025
6.0	12/13/2025	292427-00025	Date of first issue: 10/02/2015

---

Result: negative  
Remarks: The test was conducted according to guideline

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 490  
Result: negative  
Remarks: The test was conducted according to guideline

Test Type: in vitro micronucleus test  
Method: OECD Test Guideline 487  
Result: negative  
Remarks: The test was conducted according to guideline

### **Carcinogenicity**

Not classified based on available information.

### **Reproductive toxicity**

Not classified based on available information.

### **Components:**

#### **Nicotinamide:**

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: negative

#### **Pyridoxine Hydrochloride:**

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

### **STOT-single exposure**

Not classified based on available information.

### **STOT-repeated exposure**

Not classified based on available information.

### **Repeated dose toxicity**

### **Components:**

#### **Nicotinamide:**

Species : Rat  
NOAEL : 215 mg/kg  
Application Route : Ingestion  
Exposure time : 28 Days  
Method : OECD Test Guideline 407

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Vitamin B Formulation

Version 6.0      Revision Date: 12/13/2025      SDS Number: 292427-00025      Date of last issue: 12/06/2025  
Date of first issue: 10/02/2015

---

### Aspiration toxicity

Not classified based on available information.

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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

##### **Nicotinamide:**

- Toxicity to fish : LC50 (Poecilia reticulata (guppy)): > 1,000 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1,000 mg/l  
Exposure time: 24 h  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 1,000 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- NOEC (Desmodesmus subspicatus (green algae)): 560 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- Toxicity to microorganisms : NOEC (Pseudomonas putida): 4,235 mg/l  
Exposure time: 18 h  
Method: OECD Test Guideline 209

##### **Pyridoxine Hydrochloride:**

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: The test was conducted according to guideline
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: The test was conducted according to guideline
- Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 72 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: The test was conducted according to guideline
- EC10 (Desmodesmus subspicatus (green algae)): 3.3 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: The test was conducted according to guideline
- Toxicity to microorganisms : NOEC (activated sludge): >= 1,000 mg/l

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Vitamin B Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/06/2025
6.0	12/13/2025	292427-00025	Date of first issue: 10/02/2015

---

Exposure time: 30 min  
Test substance: Neutralized product  
Method: OECD Test Guideline 209  
Remarks: The test was conducted according to guideline

### Persistence and degradability

#### Components:

##### **Nicotinamide:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 95 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301E

##### **Pyridoxine Hydrochloride:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 94 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301E  
Remarks: The test was conducted according to guideline

### Bioaccumulative potential

#### Components:

##### **Nicotinamide:**

Partition coefficient: n-octanol/water : log Pow: -0.38

##### **Pyridoxine Hydrochloride:**

Partition coefficient: n-octanol/water : log Pow: -0.7  
Method: OECD Test Guideline 107  
Remarks: The test was conducted according to guideline

#### **Mobility in soil**

No data available

#### **Other adverse effects**

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### **Disposal methods**

Waste from residues : Do not dispose of waste into sewer.  
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.

## Vitamin B Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/06/2025
6.0	12/13/2025	292427-00025	Date of first issue: 10/02/2015

---

### 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

##### TDG

Not regulated as a dangerous good

#### Special precautions for user

Not applicable

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### SECTION 15. REGULATORY INFORMATION

#### The ingredients of this product are reported in the following inventories:

AICS : not determined

CA. DSL : not determined

IECSC : not determined

#### Canadian lists

No substances are subject to CEPA Section 84 Ministerial Conditions.

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### SECTION 16. OTHER INFORMATION

#### Full text of other abbreviations

AllC - Australian Inventory of Industrial Chemicals; 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 Standardization; 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 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 Chemi-

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Vitamin B Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 12/06/2025
6.0	12/13/2025	292427-00025	Date of first issue: 10/02/2015

---

cal Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organization 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; MERCOSUR - The Agreement for the Facilitation of the Transport of Dangerous Goods; 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 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, Authorization and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

Revision Date : 12/13/2025  
Date format : mm/dd/yyyy

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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