



Revision Number: 6

# Nplate® Safety Data Sheet

Date Issued 27-Mar-2020

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERSTANDING

### 1.1 Product identifier

**Product Name:** Nplate®  
**Common Name:** Romiplostim  
**Chemical Name:** Methionyl, 227 amino acid C-terminal, Immunoglobulin G1(human Fc fragment) Fusion Protein with 41 amino acid, dimer  
**Synonyms:** AMG 531

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

**Recommended Use:** Pharmaceutical  
**Uses advised against:** No information available

**Manufacturer:** Amgen Inc.  
One Amgen Center Drive  
Thousand Oaks, California 91320-1799  
1-805-447-7233  
1-805-447-1000

**Emergency Telephone Number:** Chemtrec  
NORTH AMERICA 1-800-424-9300,  
INTERNATIONAL 1-703-527-3887

## 2. HAZARDS IDENTIFICATION

### Emergency Overview

Pharmaceutical product intended for clinical and manufacturing purposes only. Product contains romiplostim (a Fc fusion protein that is expressed by recombinantly engineered E. coli) an active pharmaceutical ingredient for treatment of immune (idiopathic) thrombocytopenic purpura (ITP). Dosage contents may pose a health hazard only if significant absorption occurs (e.g., inhalation after major spill or leak). Avoid inhalation, skin contact, eye contact and accidental ingestion. Does not meet GHS classification criteria and therefore is not classified.

### 2.1 - Classification of the drug substance or mixture (drug product in final form, not applicable) REGULATION (EC) No 1272/2008

Not classified Does not meet GHS Classification Criteria and therefore is not classified.

### 2.2 Label elements

Not classified Does not meet GHS Classification Criteria and therefore is not classified.

### 2.3 Other Hazards No information available



# Nplate®

## Safety Data Sheet

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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

<b>Ingredients:</b>	Romiplostim is supplied as a lyophilized white powder ready for reconstitution in vial containing 125, 250 or 500 micrograms of deliverable drug product with mannitol, sucrose, histidine, and polysorbate 20.
<b>Chemical Name:</b>	Methionyl, 227 amino acid C-terminal, Immunoglobulin G1(human Fc fragment) Fusion Protein with 41 amino acid, dimer
<b>CAS-No:</b>	267639-76-9

### 4. FIRST AID MEASURES

#### 4.1 Description of first-aid measures

<b>Eye Contact:</b>	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
<b>Skin Contact:</b>	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Consult a physician if necessary.
<b>Inhalation:</b>	Move to fresh air. If symptoms persist, call a physician.
<b>Ingestion:</b>	If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.
<b>Notes to Physician:</b>	Treat symptomatically.

### 5. FIRE-FIGHTING MEASURES

#### 5.1 Extinguishing media

<b>Flammable Properties:</b>	Not applicable.
<b>Extinguishing Media:</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

#### 5.2 Special hazards arising from the substance or mixture

**Hazardous Combustion Products:** No information available.

#### 5.3 Advice for firefighters

**Protective Equipment and Precautions for Firefighters:** As in any fire, wear self-contained breathing apparatus pressure-demand, NIOSH (approved) and full protective gear.



# Nplate® Safety Data Sheet

Revision Number: 6

Date Issued 27-Mar-2020

## 6. ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

**Spill Procedures:**

If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment in cleaning up a spill. If in powder form, wet down spilled material to minimize airborne dispersion. Soak up material with absorbent e.g., paper towels, and wash spill area thoroughly with appropriate cleaning materials. Dispose of collected material in accordance with applicable waste disposal regulations. Avoid release to the environment.

## 7. HANDLING AND STORAGE

### 7.1 Precautions for Safe Handling

**Handling and Storage:**

Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke in work areas. Use adequate ventilation to minimize exposure. Wash hands, face and other potentially exposed areas immediately after handling this material. Remove contaminated clothing prior to entering eating areas. Clean protective equipment thoroughly after each use. Store in a well ventilated area.



# Nplate®

## Safety Data Sheet

Revision Number: 6

Date Issued 27-Mar-2020

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

**Occupational Exposure Limit:** No exposure guidelines established by ACGIH, NIOSH or OSHA. Amgen recommends an occupational exposure limit (OEL) of 40 µg/m<sup>3</sup> as an 8-hour time weighted average over a 40-hour work week. The OEL is designed as an acceptable airborne concentration of a substance for which it is believed that workers may be repeatedly exposed day after day without adverse health effects. Romiplostim has been classified per Amgen's Hazard Classification System as an Occupational Exposure Band 3 compound (20 µg/m<sup>3</sup> - 100 µg/m<sup>3</sup>).

**Engineering Controls:** When practicable, handle material in enclosed processes or in processes with effective local exhaust ventilation or within a chemical hood.

#### 8.2 Exposure controls

##### Personal Protective Equipment

**Eye/face Protection:** Wear safety glasses with side shields, chemical splash goggles, or safety glasses with side shields and a full-face shield to prevent contact with eyes. The choice of protection should be based on the job activity and potential for exposure to the eyes and face.

**Skin Protection:** Use gloves or other appropriate personal protective equipment if skin contact with formulation is possible. Wear lab coat or other protective over garment if splashing is possible. The choice of protection should be based on the job activity and potential for skin contact.

**Respiratory Protection:** When possible, handle material in enclosed processes or containers. If it is properly handled with effective local exhaust ventilation or containment, respiratory protection may not be needed. For procedures involving larger quantities or dust/aerosol generating procedures such as weighing or a large transfer of liquids, an air-purifying respirator with NIOSH approval for dusts and mists may be needed. The choice of protection should be based on the job activity and the potential for exposure.

**Other:** Wash hands, face and other potentially exposed areas after handling material (especially before eating, drinking or smoking). Clean protective equipment thoroughly after each use.

#### 8.3 Environmental exposure controls

**Environmental Exposure Controls** Avoid release to the environment.



# Nplate®

## Safety Data Sheet

Revision Number: 6

Date Issued 27-Mar-2020

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	White
<b>Physical State:</b>	Lyophilized powder
<b>Molecular Weight:</b>	~60 kD
<b>Odor:</b>	No information available
<b>Odor Threshold:</b>	No information available
<b>pH:</b>	5.0
<b>Melting Point:</b>	No information available
<b>Flash Point:</b>	Not applicable
<b>Evaporation Rate:</b>	No information available
<b>Lower explosive limit:</b>	No information available
<b>Upper explosive limit:</b>	No information available
<b>Vapor Pressure:</b>	Not applicable
<b>Vapor Density (air = 1):</b>	Not applicable
<b>Relative density:</b>	No information available
<b>Water Solubility:</b>	No information available
<b>Partition Coefficient (log Kow):</b>	No information available
<b>Viscosity:</b>	No information available

### 10. STABILITY AND REACTIVITY

<b>10.1 Reactivity</b>	No information available
<b>10.2 Chemical stability</b>	Stable
<b>10.3 Possibility of hazardous reactions</b>	No information available
<b>10.4 Conditions to avoid</b>	No Information available
<b>10.5 Incompatible materials</b>	No information available
<b>10.6 Hazardous decomposition products</b>	No information available
<b>10.7 Other information</b>	None
<b>Dust Explosion Properties:</b>	No information available



# Nplate® Safety Data Sheet

Revision Number: 6

Date Issued 27-Mar-2020

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

<b>Acute Toxicity:</b>	Does not meet GHS Classification Criteria and therefore is not classified.
<b>Skin corrosion/irritation:</b>	Does not meet GHS Classification Criteria and therefore is not classified.
<b>Serious eye damage/eye irritation:</b>	Does not meet GHS Classification Criteria and therefore is not classified.
<b>Respiratory or skin sensitization:</b>	Does not meet GHS Classification Criteria and therefore is not classified.
<b>Germ cell mutagenicity:</b>	Does not meet GHS Classification Criteria and therefore is not classified.
<b>Carcinogenicity:</b>	Does not meet GHS Classification Criteria and therefore is not classified.
<b>Reproductive toxicity:</b>	Based on available data, the GHS classification criteria are not met.
<b>STOT - single exposure:</b>	Based on available data, the GHS classification criteria are not met.
<b>STOT - repeated exposure:</b>	Based on available data, the GHS classification criteria are not met.
<b>Aspiration Hazard:</b>	No information available

## 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity

**Ecotoxicity effects:** No information available

### 12.2 Persistence and degradability

**Persistence/Degradability:** No information available

### 12.3 Bioaccumulative potential

**Bioaccumulation/ Accumulation:** No information available

### 12.4 Mobility in soil

**Mobility in Environmental Media:** No information available

### 12.5 Results of PBT and vPvB assessment

**Results of PBT and vPvB assessment:** No information available

### 12.6 Other adverse effects

**Other Adverse Effects:** No information available

## 13. DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

**Waste Disposal Method:** Dispose of waste according to prescribed federal, state, local and competent authority guidelines.



# Nplate® Safety Data Sheet

Revision Number: 6

Date Issued 27-Mar-2020

## 14. TRANSPORT INFORMATION

**DOT:** Not regulated by U.S. DOT, IATA, or IMDG.

## 15. REGULATORY INFORMATION

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

#### International Inventories

<b>TSCA:</b>	-
<b>EINECS/ELINCS</b>	-
<b>DSL/NDSL</b>	-
<b>PICCS:</b>	-
<b>ENCS:</b>	-
<b>CHINA:</b>	-
<b>AICS:</b>	-
<b>KECL:</b>	-

#### Legend

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances

#### State Regulations

**California Proposition 65:** This product does not contain any Proposition 65 chemicals.

### 15.2 Chemical safety assessment

No CSA has been conducted.



# Nplate® Safety Data Sheet

Revision Number: 6

Date Issued 27-Mar-2020

## 16. OTHER INFORMATION

Revision Number: 6

To the best of our knowledge, the information provided here is accurate as of the date of the Safety Data Sheet (SDS). The information is specific to the material that is the subject of this SDS and may not be valid when this material is used in combination with any other materials or in any process. Each user should review the information provided here in the context of the user's intended manner of handling, using, processing, storing, transporting, and disposing of the material.

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