



Revision Number: 5

# Nplate<sup>®</sup> Safety Data Sheet

Date Issued 20-Feb-2018

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

### 1.1 Product identifier

**Product Name:** Nplate  
**Common Name:** Romiplostim  
**Chemical Name:** Not Applicable  
**Synonyms:** No information available

### 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

**Classification according to EU Directives 67/548/EEC or 1999/45/EC**  
*For the full text of the R phrases mentioned in this Section, see Section 16*

### 2.2 Label elements

Not classified

### 2.3 Other Hazards

No information available



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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

**Ingredients:** Proprietary information

**Chemical Name:** Not Applicable

**CAS-No:** 267639-76-9

#### Single use vial containing 125 µg of Nplate<sup>®</sup> supplied as a lyophilized dosage form with:

	CAS Number:	Amount
Romiplostin	267639-76-9	230 µg
Mannitol	87-78-5	18 mg
Sucrose	57-50-1	9 mg
Histidine	71-00-1	0.7 mg
Polysorbate 20	9005-64-5	0.02 mg

#### Single use vial containing 250 µg of Nplate<sup>®</sup> supplied as a lyophilized dosage form with:

	CAS Number:	Amount
Romiplostin	267639-76-9	375 µg
Mannitol	87-78-5	30 mg
Sucrose	57-50-1	15 mg
Histidine	71-00-1	1.2 mg
Polysorbate 20	9005-64-5	0.03 mg

#### Single use vial containing 500 µg of Nplate<sup>®</sup> supplied as a lyophilized dosage form with:

	CAS Number:	Amount
Romiplostin	267639-76-9	625 µg
Mannitol	87-78-5	50 mg
Sucrose	57-50-1	25 mg
Histidine	71-00-1	1.9 mg
Polysorbate 20	9005-64-5	0.05 mg

### 4. FIRST AID MEASURES

#### 4.1 Description of first-aid measures

**Eye Contact:** In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

**Skin Contact:** Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Consult a physician if necessary.

**Inhalation:** Move to fresh air. If symptoms persist, call a physician.

**Ingestion:** If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

**Notes to Physician:** Treat symptomatically.



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### 5. FIRE-FIGHTING MEASURES

#### 5.1 Extinguishing media

**Flammable Properties:** Not applicable.

**Extinguishing Media:** 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.

### 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.



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### 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. Nplate<sup>®</sup> 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.



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### 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 (when reconstituted)
<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



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### 11. TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

<b>Acute Toxicity:</b>	No information available
<b>Skin corrosion/irritation:</b>	No information available
<b>Serious eye damage/eye irritation:</b>	No information available
<b>Respiratory or skin sensitization:</b>	No information available
<b>Germ cell mutagenicity:</b>	No information available
<b>Carcinogenicity:</b>	No information available
<b>Reproductive toxicity:</b>	Even though this does not meet GHS classification, the following data is available: developmental toxicity has been observed from subcutaneous administration in animal studies. In mice increased postimplantation loss occurred at the same dose as a reduction in maternal weight gain.
<b>STOT - single exposure:</b>	Even though this does not meet GHS classification, the following data is available: Single dose toxicity and safety pharmacology studies with Nplate <sup>®</sup> administered parenterally did not identify any adverse effects. However, pharmacodynamic effects of increased platelet count, increased spleen to body weight ratio, and increased extramedullary hematopoiesis were observed.
<b>STOT - repeated exposure:</b>	Even though this does not meet GHS classification, the following data is available: Four week, multiple-dose toxicology studies with Nplate <sup>®</sup> were conducted in rats, and rhesus and cynomolgus monkeys. The drug was generally well-tolerated at doses up to 100 µg/kg (rats) or 5,000 µg/kg (monkeys). In general, findings were related to the thrombopoietic activity of Nplate <sup>®</sup> and included extramedullary hematopoiesis, femoral and sternal bone hyperostosis, marrow myelofibrosis (rats only), and megakaryocytosis. All findings reversed or were absent after a 4-week recovery period. Single doses of Nplate <sup>®</sup> have been effective in increasing platelet counts above baseline values without any identified safety issues in healthy humans. In clinical trials, the most common treatment-related events among patients with immune thrombocytopenia purpura (ITP) were headache, myalgia, and injection site bruising. Target organs include: Blood, bone, central nervous system (CNS), gastrointestinal tract (GI), Musculoskeletal
<b>Aspiration Hazard:</b>	No information available



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## 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.

## 14. TRANSPORT INFORMATION

DOT Not regulated by U.S. DOT or IATA



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### 15. REGULATORY INFORMATION

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

##### International Inventories

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

##### 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.

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 2

No information available

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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 may be biologically active.