

# Safety Data Sheet

acc. to HCS and GHS

Printing date 12/29/2014

Reviewed on 12/29/2014

## 1 Identification

- **Product identifier**
- **Trade name: 4-Way® Nasal Spray**
- **Application of the substance / the mixture** Pharmaceutical Product
- **Details of the supplier of the Safety Data Sheet**
- **Manufacturer/Supplier:**  
Novartis Consumer Health, Inc.  
200 Kimball Drive  
Parsippany, NJ 07054  
USA
- **Information department:**  
Novartis Consumer and Professional Affairs Call Center  
(800) 452-0051 (24 hours / 7 days a week)
- **Emergency telephone number:**  
ChemTel Inc.  
(800)255-3924, +1 (813)248-0585



## 2 Hazard(s) identification

- **Classification of the substance or mixture**  
The product is not classified as hazardous according to the Globally Harmonized System (GHS).
- **Label elements**
- **GHS label elements** Not Regulated
- **Hazard pictograms** Not Regulated
- **Signal word** Not Regulated
- **Hazard-determining components of labeling:** None.
- **Hazard statements** Not Regulated
- **Hazard description:**
- **WHMIS-symbols:** Not hazardous under WHMIS.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**

	Health = 0
	Fire = 0
	Reactivity = 0
- **HMIS-ratings (scale 0 - 4)**

	Health = 0
	Fire = 0
	Reactivity = 0
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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### 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

61-76-7	phenylephrine hydrochloride ☠ Acute Tox. 3, H301	≤ 2.5%
100-51-6	Benzyl alcohol ☠ Acute Tox. 4, H302; Acute Tox. 4, H332	≤ 2.5%

- **Dangerous Components (Alternative Classifications):**

61-76-7	phenylephrine hydrochloride ☠ Acute Tox. 3, H301	≤ 2.5%
100-51-6	Benzyl alcohol ☠ Acute Tox. 4, H302; Acute Tox. 4, H332	≤ 2.5%
10043-35-3	boric acid ☠ Repr. 1B, H360	≤ 2.5%
8001-54-5	benzalkonium chloride ☠ Skin Corr. 1B, H314; Eye Dam. 1, H318 ☠ Aquatic Acute 1, H400 ☠ Acute Tox. 4, H302; Acute Tox. 4, H312	≤ 2.5%
1303-96-4	Disodium tetraborate, decahydrate ☠ Repr. 1B, H360	≤ 2.5%

### 4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**  
Clean with water and soap.  
If skin irritation continues, consult a doctor.
- **After eye contact:**  
Remove contact lenses if worn.  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:**  
Rinse out mouth and then drink plenty of water.  
Do not induce vomiting; immediately call for medical help.
- **Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **Danger** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

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### 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **For safety reasons unsuitable extinguishing agents:** None.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.
- **Additional information** No further relevant information available.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose contaminated material as waste according to item 13.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### 7 Handling and storage

- **Precautions for safe handling** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**  
Store in a cool location.  
Avoid storage near extreme heat, ignition sources or open flame.
- **Information about storage in one common storage facility:** No special requirements.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

<b>Components with limit values that require monitoring at the workplace:</b>
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100-51-6 Benzyl alcohol
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WEEL (USA)   Long-term value: 10 ppm
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- **Additional information:** The lists that were valid during the creation were used as basis.

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- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures for handling chemicals should be followed.  
No further relevant information available.
- **Breathing equipment:** Not required.
- **Protection of hands:** Not required.
- **Eye protection:** Not required under normal conditions of use.
- **Body protection:** Not required.
- **Limitation and supervision of exposure into the environment** No special requirements.

### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
  - **Form:** Liquid
  - **Color:** Colorless
- **Odor:** Pleasant
- **Odor threshold:** Not determined.
- **pH-value:** Not determined.
- **Change in condition**
  - **Melting point/Melting range:** Undetermined.
  - **Boiling point/Boiling range:** 212 °F / 100 °C (414 °F / 212 °F)
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Not applicable.
- **Auto-ignition temperature:** Not determined.
- **Decomposition temperature:** Not determined.
- **Auto igniting:** Product is not self-igniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**
  - **Lower:** Not determined.
  - **Upper:** Not determined.
- **Vapor pressure at 20 °C (68 °F):** 23 hPa (17 mm Hg)
- **Density at 20 °C (68 °F):** 1 g/cm<sup>3</sup> (8.345 lbs/gal)
- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.
- **Solubility in / Miscibility with**
  - **Water:** Fully miscible.

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- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
  - Dynamic:** Not determined.
  - Kinematic:** Not determined.
- **Solvent content:**
- **VOC content:** 0.1 %
- **Other information** No further relevant information available.

### 10 Stability and reactivity

- **Reactivity**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used and stored according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Possible in traces.

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
  - **on the skin:** No irritant effect.
  - **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**  
The product is not subject to classification according to internally approved calculation methods for preparations:  
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
- **Carcinogenic categories**

#### · **NTP (National Toxicology Program)**

None of the ingredients is listed.

#### · **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.

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- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**  
Can be burned with household garbage after consulting with the waste disposal facility operator and the pertinent authorities and adhering to the necessary technical regulations.  
Smaller quantities can be disposed of with household waste.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

### 14 Transport information

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** Not Regulated
- **UN proper shipping name**
- **DOT, ADR, ADN, IMDG, IATA** Not Regulated
- **Transport hazard class(es)**
- **DOT, ADR, ADN, IMDG, IATA**
- **Class** Not Regulated
- **Packing group**
- **DOT, ADR, IMDG, IATA** Not Regulated
- **Environmental hazards:**
- **Marine pollutant:** No
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.
- **UN "Model Regulation":** -

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **SARA**

**Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

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· **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

· **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

· **Proposition 65 (California)**

· **Chemicals known to cause cancer:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

10043-35-3	boric acid	A4
1303-96-4	Disodium tetraborate, decahydrate	A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **State Right to Know Listings**

None of the ingredients is listed.

· **Canadian substance listings:**

· **Canadian Domestic Substances List (DSL)**

All ingredients are listed.

· **Canadian Ingredient Disclosure list (limit 0.1%)**

None of the ingredients is listed.

· **Canadian Ingredient Disclosure list (limit 1%)**

None of the ingredients is listed.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Date of preparation / last revision** 12/29/2014 / -

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**· Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

ACGIH: American Conference of Governmental Industrial Hygienists

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

WHMIS: Workplace Hazardous Materials Information System (Canada)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

Acute Tox. 3: Acute toxicity, Hazard Category 3

Acute Tox. 4: Acute toxicity, Hazard Category 4

**· Sources**

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