

**Product Name:** Duopa  
**Issued:** Nov-03-2015



## **SAFETY DATA SHEET**

### **Section 1. Identification of the substance/mixture and of the company/undertaking**

#### **1.1 Product Identifier**

**Product Name:** Duopa  
**Synonyms:** Duodopa; Levodopa-Carbidopa Intestinal Gel; Duodopa Intestinal Gel 20 mg/5 mg per mL; Duodopa Intestinal Gel 40 mg/10 mg per mL  
**List Number:** W152

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

**Recommended use:** Pharmaceuticals

#### **1.3 Details of the supplier of the safety data sheet**

**Supplier:** Manufactured for:  
AbbVie Inc.  
1 North Waukegan Road  
North Chicago, IL 60064  
USA  
+1-847-932-7900  
**Customer Service Telephone:** 1-800-255-5162 (US and Canada only)  
+1-847-937-7433  
**E-mail Address:** AbbVie.SDS@abbvie.com

#### **1.4 Emergency telephone number**

**Emergency Telephone:** CHEMTREC: 1(800) 424-9300 (in USA and Canada)  
or +1-703-527-3887 (international)

### **Section 2. Hazards identification**

#### **2.1 Classification of the substance or mixture**

**Regulation (EC) No 1272/2008**

**Reproductive toxicity** Category 2

**Classification according to EU Directives 67/548/EEC or 1999/45/EC**

**Indication of danger:** Xn - Harmful

**Risk Phrases:** R63 - Possible risk of harm to the unborn child

#### **2.2 Label elements**

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**Signal Word:** Warning

**Hazard Statements:**  
H302 - Harmful if swallowed  
H319 - Causes serious eye irritation  
H361 - Suspected of damaging fertility or the unborn child

**Precautionary Statements**  
P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P281 - Use personal protective equipment as required  
P308 + P313 - IF exposed or concerned: Get medical advice/attention  
P405 - Store locked up

### 2.3 Other hazards

Not determined

## **Section 3. Composition/information on ingredients**

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Carboxymethylcellulose Sodium 9004-32-4	70-90	NA		Not Hazardous*	No data available
Water 7732-18-5	5-20	Present		Not Hazardous*	No data available
Levodopa 59-92-7	1-5	Present	Xn, R22; Xi, R36; R63	Eye Irrit. 2 (H319) Acute Tox. 4 (H302) Repro 2 (H361)	No data available
Carbidopa 28860-95-9	0.1-5	Present		Not Hazardous*	No data available

Not Hazardous\* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

**For the full text of the R-phrases mentioned in this Section, see Section 16**

**For the full text of the H-Statements mentioned in this Section, see Section 16**

## **Section 4. First aid measures**

### 4.1 Description of first aid measures

**Eye Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

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**Skin Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Inhalation:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Ingestion:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Protection of First-aiders:** Use personal protective equipment

#### **4.2 Most important symptoms and effects, both acute and delayed**

**Signs and Symptoms:** Clinical data suggests the following: variable central nervous system effects, vomiting, nausea, hypotension, cardiac changes.

**Medical Conditions Aggravated by Exposure:** None known from occupational exposure.

#### **4.3 Indication of any immediate medical attention and special treatment needed**

**Notes To Physician:** Treat symptomatically

### **Section 5. Firefighting measures**

#### **5.1 Extinguishing Media**

**Suitable Extinguishing Media:** Use extinguishing agent suitable for type of surrounding fire

**Unsuitable Extinguishing Media:** Not determined

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

**Special Exposure Hazards:** Not determined

#### **5.3 Advice for firefighters**

**Protective Equipment and Precautions for Firefighters:** As in any fire, wear self-contained breathing apparatus and full protective gear

### **Section 6. Accidental release measures**

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

**Personal Precautions:** For personal protection see section 8.

#### **6.2. Environmental precautions**

**Environmental Precautions:** Contain material and prevent release to waterways or soil.

#### **6.3. Methods and material for containment and cleaning up**

**Methods for Cleaning Up:** Recover product and place in an appropriate container for disposal.

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#### **6.4. Reference to other sections**

Refer to Sections 8, 12, and 13 for further information.

### **Section 7. Handling and storage**

#### **7.1. Precautions for safe handling**

Handle in accordance with good industrial hygiene and safety practice.

#### **7.2. Conditions for safe storage, including any incompatibilities**

Store according to label instructions.

#### **7.3. Specific end use(s)**

**Recommended use:** Pharmaceuticals

### **Section 8. Exposure controls/personal protection**

#### **8.1. Control parameters**

##### **Exposure limits:**

<b>Chemical Name</b>	<b>Employee Exposure Limit</b>	<b>Skin Notation</b>
Carboxymethylcellulose Sodium 9004-32-4	Not Applicable	None
Water 7732-18-5	Not Applicable	None
Levodopa 59-92-7	330 mcg/m <sup>3</sup>	None
Carbidopa 28860-95-9	33 mcg/m <sup>3</sup>	None

<b>Chemical Name</b>	<b>ACGIH TLV</b>	<b>France</b>	<b>German MAK</b>	<b>Ireland</b>	<b>Italy</b>
Carboxymethylcellulose Sodium 9004-32-4	10 mg/m <sup>3</sup> total dust; 3 mg/m <sup>3</sup> respirable dust				

#### **8.2. Exposure controls**

**Engineering Controls:** No special provisions are required under normal product use conditions. When handling bulk formulation, use in a well-ventilated area.

**Respiratory Protection:** Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

**Eyes:** Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.

**Gloves:** Not needed during typical product use conditions. Wear impervious gloves when handling the bulk formulation.

**Other PPE Data:** Not determined.

**Environmental Exposure Controls:** Not determined

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## **Section 9. Physical and chemical properties**

### **9.1. Information on basic physical and chemical properties**

<b>Appearance:</b>	Off-white to light yellow Gel
<b>Odor:</b>	Not determined.
<b>Odor Threshold:</b>	Not determined
<b>pH:</b>	Not determined.
<b>Boiling Pt. @ 760 mm Hg (°C):</b>	Not determined.
<b>Melting/Freezing Point (°C):</b>	Not determined
<b>Flash Point (°C):</b>	Not determined.
<b>Evaporation Rate at 20°C:</b>	Not determined.
<b>Flammability (Solid):</b>	Not determined.
<b>Lower Explosive Limit:</b>	Not determined.
<b>Upper Explosive Limit:</b>	Not determined.
<b>Vapor Pressure (mm Hg):</b>	Not determined.
<b>Vapor Density (Air = 1):</b>	Not determined.
<b>Specific Gravity:</b>	Not determined.
<b>Solubility(ies):</b>	Not determined.
<b>Partition coefficient: n-octanol/water</b>	Not determined.
<b>Autoignition Temp. (°C):</b>	Not determined.
<b>Decomposition temperature (°C):</b>	Not determined.
<b>Viscosity (centipoise):</b>	Not determined.
<b>Explosion Severity:</b>	Not determined.
<b>Oxidizer Properties:</b>	Not determined.

### **9.2. Other information**

Not determined

## **Section 10. Stability and reactivity**

### **10.1. Reactivity**

Not determined

### **10.2. Chemical stability**

Stable under normal conditions

### **10.3. Possibility of hazardous reactions**

**Hazardous reactions:** Not determined.

### **10.4. Conditions to avoid**

Not determined.

### **10.5 Incompatible materials**

Not determined

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## 10.6 Hazardous decomposition products

Carbon oxides

## Section 11. Toxicological information

### 11.1. Information on toxicological effects

#### Routes of Exposure:

**Oral:** Clinical Route  
**Dermal:** Unlikely  
**Inhalation:** Unlikely

**Acute Toxicity - Oral:** Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Carboxymethylcellulose Sodium 9004-32-4	LD50 =	19000 27000	mg/kg	Guinea Pigs Mice Rabbits
Levodopa 59-92-7	LD50 =	1780 2363	mg/kg	Rats Mice
Carbidopa 28860-95-9	LD50 =	1750 4810	mg/kg	Mice Rats

**Acute Toxicity - Dermal:** Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Carboxymethylcellulose Sodium 9004-32-4	LD50 >	2000	mg/kg	Rabbits

**Acute Toxicity - Inhalation:** Data for component (s) given below.

Chemical Name	Test	Value	Units	Species
Carboxymethylcellulose Sodium 9004-32-4	LC 50 >	5800	mg/m <sup>3</sup>	Rats

**Other Toxicology Data:** Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Levodopa 59-92-7	LD50 (sc) =	2000	mg/kg	Rats	
Carbidopa 28860-95-9	LD50 (ip) =	2804 468	mg/kg	Rats Mice	

**Corrosivity:** Not determined.

**Dermal Irritation:** Not determined.

**Eye Irritation:** Active Ingredient : Eye irritant

**Sensitization:** Not determined.

**Toxicokinetics/Metabolism:** Not determined.

**Target Organ Effects:** Not determined.

**Reproductive Effects:** In animals adverse reproductive effects include: fetal abnormalities.

Chemical Name	Species	Dosage	Units	Route	Duration
Levodopa 59-92-7	Rabbits	125	mg/kg	Oral	During Gestation

**Carcinogenicity:** Active ingredient : Not carcinogenic in animal study.

**Mutagenicity:** Data for component (s) given below.

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Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Levodopa 59-92-7	No Data.	Positive with activation	No Data.	Positive without metabolic activation
Carbidopa 28860-95-9	Negative	Positive	Positive	Negative

**Aspiration hazard:** Not determined

**Notes:**

1. **ALD:** Approximate lethal dosage
2. **LC50:** Concentration in air that produces 50% mortality
3. **LD50:** Oral or dermal dosage that produces 50% mortality

## Section 12. Ecological information

### 12.1. Toxicity

Not determined.

### 12.2. Persistence and degradability

Not determined.

### 12.3. Bioaccumulative potential

Not determined

### 12.4. Mobility in soil

Not determined.

### 12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

### 12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

**Notes:**

1. **EC50:** Concentration in water that produces 50% mortality in *Daphnia* sp.
2. **LC50:** Concentration in water that produces 50% mortality in fish.
3. **EbC50/ErC50:** Concentration in water that produces 50% inhibition of growth and in algae.

## Section 13. Disposal considerations

### 13.1 Waste treatment methods

**Waste Disposal Methods:** Disposal should be made in accordance with country, federal, state and local regulations.

## Section 14. Transport information

### ADR, DOT, ICAO/IATA, IMDG/IMO

**Status:** Not regulated

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**14.1. UN Number:** Not applicable  
**14.2. Proper shipping name:** Not applicable  
**14.3. Hazard class:** Not applicable  
**14.4. Packing group:** Not applicable  
**14.5. Environmental hazard:** Not applicable  
**14.6. Special Provisions:** Not applicable  
**14.7. Transport in bulk** Not applicable  
**according to Annex II of**  
**MARPOL 73/78 and the IBC**  
**Code:**

## Section 15. Regulatory Information

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

#### International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Carboxymethylcellulose Sodium 9004-32-4	-	X	X	Not listed.	X
Water 7732-18-5	Present	X	X	Not listed.	X
Levodopa 59-92-7	Present	X	-	X	X
Carbidopa 28860-95-9	Present	-	X	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Carboxymethylcellulose Sodium 9004-32-4	Present	Present	X	X	Present	HSR003136
Water 7732-18-5	-	-	X	X	Present	
Levodopa 59-92-7	Present	Present	X	X	Present	HSR006231
Carbidopa 28860-95-9	-	Present	-	-	-	

#### Legend

**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**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

**ISHL** - Japan Industrial Safety and Health Law

**IECSC** - China Inventory of Existing Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

#### Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Carboxymethylcellulose Sodium	70-90	Not Listed	Not Listed	Not Listed
Water	5-20	Not Listed	Not Listed	Not Listed
Levodopa	1-5	Not Listed	Not Listed	Not Listed
Carbidopa	0.1-5	Not Listed	Not Listed	Not Listed

#### SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
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Carboxymethylcellulose Sodium	70-90	No	Not Applicable	Not applicable
Water	5-20	No	Not Applicable	Not applicable
Levodopa	1-5	No	Not Applicable	Not applicable
Carbidopa	0.1-5	No	Not Applicable	Not applicable

**Immediate Health:** No

**Delayed Health:** No

**Fire:** No

**Sudden Pressure:** No

**Reactivity:** No

**RCRA Status:** Not determined.

**Proposition 65 Status:** Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

Component	Percent	Proposition 65 Listed Materials
Levodopa 59-92-7 ( 1-5 )	1-5	developmental toxicity, initial date 1/29/99

**WHMIS Hazard Class:** Not determined.

**NFPA Rating:**

Health: 0

Fire: 1

Reactivity: 0

**Notes:**

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

## 15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

## **Section 16. Other information**

**Risk Phrases:**

R63 - Possible risk of harm to the unborn child

**Full text of H-Statements referred to under sections 2 and 3**

H319 - Causes serious eye irritation

H302 - Harmful if swallowed

H361 - Suspected of damaging fertility or the unborn child if inhaled

**Document Authored By:** Occupational and Environmental Toxicology

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**Supersedes the SDS dated:** Sep-08-2014

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