SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name : Carbidopa / Levodopa Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company : Organon & Co.
Shotton Lane
NE23 3JU Cramlington NU - Great Britain
Telephone : 44 1 670 59 30 00
E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number
215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Acute toxicity, Category 4 H302: Harmful if swallowed.
Reproductive toxicity, Category 2 H361d: Suspected of damaging the unborn child.
Specific target organ toxicity - repeated exposure, Category 1 H372: Causes damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 3 H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms :

Signal word : Danger
Hazard statements : H302 Harmful if swallowed.
H361d Suspected of damaging the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.
H412 Harmful to aquatic life with long lasting effects.
Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
P260 Do not breathe dust.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Hazardous components which must be listed on the label:
Levodopa
Carbidopa

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levodopa</td>
<td>59-92-7 200-445-2</td>
<td>Acute Tox. 4; H302 Repr. 2; H361d STOT RE 1; H372 (Central nervous system) Aquatic Chronic 3; H412</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td>Carbidopa</td>
<td>38821-49-7</td>
<td>Acute Tox. 4; H302 Aquatic Chronic 3; H412</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

If inhaled: If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact: If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed
Risks: Harmful if swallowed.
Suspected of damaging the unborn child.
Causes damage to organs through prolonged or repeated exposure.

Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during fire-
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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fighting concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides
- Metal oxides

5.3 Advice for firefighters
Special protective equipment for firefighters:
In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.

SECTION 6: Accidental release measures

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

6.2 Environmental precautions
Environmental precautions:
Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up
Methods for cleaning up:
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.
SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures:
- Static electricity may accumulate and ignite suspended dust causing an explosion.
- Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation:
- Use only with adequate ventilation.

Advice on safe handling:
- Do not breathe dust.
- Do not swallow.
- Avoid contact with eyes.
- Avoid prolonged or repeated contact with skin.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Do not eat, drink or smoke when using this product.
- Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures:
- 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.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
- Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.

Advice on common storage:
- Do not store with the following product types:
  - Strong oxidizing agents
  - Organic peroxides
  - Explosives
  - Gases

7.3 Specific end use(s)

Specific use(s):
- No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits
## Components

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levodopa</td>
<td>59-92-7</td>
<td>TWA</td>
<td>500 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Carbidopa</td>
<td>38821-49-7</td>
<td>TWA</td>
<td>2,000 µg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA (inhalable dust)</td>
<td>10 mg/m³</td>
<td>GB EH40</td>
</tr>
</tbody>
</table>

Further information: For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols. The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m⁻³ 8-hour TWA of inhalable dust or 4 mg.m⁻³ 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits. Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed ‘inhalable’ and ‘respirable’. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4. Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with.

<table>
<thead>
<tr>
<th>TWA (Respirable dust)</th>
<th>4 mg/m³</th>
<th>GB EH40</th>
</tr>
</thead>
<tbody>
<tr>
<td>STEL (inhalable dust)</td>
<td>20 mg/m³</td>
<td>GB EH40</td>
</tr>
</tbody>
</table>

Further information: For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols. The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m⁻³ 8-hour TWA of inhalable dust or 4 mg.m⁻³ 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits. Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed ‘inhalable’ and ‘respirable’. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4. Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with.
sampling is undertaken in accordance with the methods described in
MDHS14/4 General methods for sampling and gravimetric analysis or respira-
table, thoracic and inhalable aerosols., The COSHH definition of a substance
hazardous to health includes dust of any kind when present at a concentration
in air equal to or greater than 10 mg.m\(^{-3}\) 8-hour TWA of inhalable dust or 4
mg.m\(^{-3}\) 8-hour TWA of respirable dust. This means that any dust will be sub-
ject to COSHH if people are exposed to dust above these levels. Some dusts
have been assigned specific WELs and exposure to these must comply with
the appropriate limits., Most industrial dusts contain particles of a wide range
of sizes. The behaviour, deposition and fate of any particular particle after
entry into the human respiratory system, and the body response that it elicits,
depend on the nature and size of the particle. HSE distinguishes two size
fractions for limit-setting purposes termed 'inhalable' and 'respirable'., Inhal-
able dust approximates to the fraction of airborne material that enters the nose
and mouth during breathing and is therefore available for deposition in the
respiratory tract. Respirable dust approximates to the fraction that penetrates
to the gas exchange region of the lung. Fuller definitions and explanatory
material are given in MDHS14/4., Where dusts contain components that have
their own assigned WEL, all the relevant limits should be complied with.

| Starch | 9005-25-8 | TWA (inhalable dust) | 10 mg/m\(^3\) | GB EH40 |

Further information: For the purposes of these limits, respirable dust and in-
halable dust are those fractions of airborne dust which will be collected when
sampling is undertaken in accordance with the methods described in
MDHS14/4 General methods for sampling and gravimetric analysis or respira-
table, thoracic and inhalable aerosols., The COSHH definition of a substance
hazardous to health includes dust of any kind when present at a concentration
in air equal to or greater than 10 mg.m\(^{-3}\) 8-hour TWA of inhalable dust or 4
mg.m\(^{-3}\) 8-hour TWA of respirable dust. This means that any dust will be sub-
ject to COSHH if people are exposed to dust above these levels. Some dusts
have been assigned specific WELs and exposure to these must comply with
the appropriate limits., Most industrial dusts contain particles of a wide range
of sizes. The behaviour, deposition and fate of any particular particle after
entry into the human respiratory system, and the body response that it elicits,
depend on the nature and size of the particle. HSE distinguishes two size
fractions for limit-setting purposes termed 'inhalable' and 'respirable'., Inhal-
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and mouth during breathing and is therefore available for deposition in the
respiratory tract. Respirable dust approximates to the fraction that penetrates
to the gas exchange region of the lung. Fuller definitions and explanatory
material are given in MDHS14/4., Where dusts contain components that have
their own assigned WEL, all the relevant limits should be complied with.,
Where no specific short-term exposure limit is listed, a figure three times the
long-term exposure limit should be used.

| TWA (Respirable dust) | 4 mg/m\(^3\) | GB EH40 |

Further information: For the purposes of these limits, respirable dust and in-
halable dust are those fractions of airborne dust which will be collected when
sampling is undertaken in accordance with the methods described in
MDHS14/4 General methods for sampling and gravimetric analysis or respira-
table, thoracic and inhalable aerosols., The COSHH definition of a substance
hazardous to health includes dust of any kind when present at a concentration
in air equal to or greater than 10 mg.m\(^{-3}\) 8-hour TWA of inhalable dust or 4
mg.m\(^{-3}\) 8-hour TWA of respirable dust. This means that any dust will be sub-
ject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits. Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed 'inhaled' and 'respirable'. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4. Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with. Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used.

8.2 Exposure controls

Engineering measures
Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Personal protective equipment

Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection
Material: Chemical-resistant gloves

Skin and body protection: Work uniform or laboratory coat.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 143

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: powder
Colour: No data available
Odour: odourless
Odour Threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling: No data available
Carbidopa / Levodopa Formulation

9.2 Other information

Molecular weight : No data available

Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.
10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Harmful if swallowed.

Product:
Acute oral toxicity: Acute toxicity estimate: 1,952 mg/kg
Method: Calculation method

Components:

Levodopa:
Acute oral toxicity: LD50 (Rat): 1,780 mg/kg
LD50 (Mouse): 2,363 mg/kg

Carbidopa:
Acute oral toxicity: LD50 (Rat): 4,810 mg/kg
LD50 (Mouse): 1,750 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:
Carbidopa:
SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006  

Carbidopa / Levodopa Formulation  

Version: 4.7  
Revision Date: 09.04.2021  
SDS Number: 51060-00017  
Date of last issue: 10.10.2020  
Date of first issue: 23.01.2015

Species: Rabbit  
Result: No skin irritation

**Serious eye damage/eye irritation**  
Not classified based on available information.

**Components:**

**Carbidopa:**  
Species: Rabbit  
Result: Mild eye irritation

**Respiratory or skin sensitisation**  

**Skin sensitisation**  
Not classified based on available information.

**Respiratory sensitisation**  
Not classified based on available information.

**Components:**

**Levodopa:**  
Species: Guinea pig  
Result: Not a skin sensitizer.

**Carbidopa:**  
Remarks: No data available

**Germ cell mutagenicity**  
Not classified based on available information.

**Components:**

**Levodopa:**  
Genotoxicity in vitro:  
- Test Type: Bacterial reverse mutation assay (AMES)  
  Result: negative

  Test Type: Chromosomal aberration  
  Test system: mouse lymphoma cells  
  Result: equivocal

  Test Type: Micronucleus test  
  Test system: Chinese hamster lung cells  
  Result: positive

  Test Type: sister chromatid exchange assay  
  Test system: Chinese hamster lung cells  
  Result: positive

**Carbidopa:**  
Genotoxicity in vitro:  
- Test Type: Bacterial reverse mutation assay (AMES)
Result: positive

Test Type: In vitro mammalian cell gene mutation test
Result: positive

Genotoxicity in vivo:
Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Levodopa:
Species: Rat
Application Route: Oral
Exposure time: 2 Years
Result: negative

Carbidopa:
Species: Rat
Application Route: Oral
Exposure time: 96 weeks
: 135 mg/kg body weight
Result: negative

Reproductive toxicity
Suspected of damaging the unborn child.

Components:

Levodopa:
Effects on fertility:
Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 100 mg/kg body weight
Result: Animal testing did not show any effects on fertility.

Effects on foetal development:
Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 125 mg/kg body weight
Symptoms: Skeletal malformations, Visceral malformations
Result: positive

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 10 mg/kg body weight

Test Type: Development
**Reproductive toxicity - Assessment**: Some evidence of adverse effects on development, based on animal experiments.

**Carbidopa**:  
**Effects on fertility**:  
- **Test Type**: Fertility  
- **Species**: Rat  
- **Application Route**: Oral  
- **Fertility**: NOAEL: 120 mg/kg body weight  
- **Symptoms**: Reduced body weight  
- **Result**: Animal testing did not show any effects on fertility.

**Effects on foetal development**:  
- **Test Type**: Development  
- **Species**: Mouse  
- **Application Route**: Oral  
- **Developmental Toxicity**: NOAEL: 120 mg/kg body weight  
- **Result**: No teratogenic effects

**Test Type**: Development  
- **Species**: Rabbit  
- **Application Route**: Oral  
- **Developmental Toxicity**: NOAEL: 120 mg/kg body weight  
- **Result**: No teratogenic effects

**STOT - single exposure**
Not classified based on available information.

**STOT - repeated exposure**
Causes damage to organs through prolonged or repeated exposure.

**Components:**

**Levodopa**:  
- **Exposure routes**: Oral  
- **Target Organs**: Central nervous system  
- **Assessment**: Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**Levodopa**:  
- **Species**: Rat  
- **LOAEL**: 100 mg/kg  
- **Application Route**: Oral  
- **Exposure time**: 106 Weeks  
- **Target Organs**: Central nervous system
Symptoms: Salivation

Species: Monkey
LOAEL: 100 mg/kg
Application Route: Oral
Exposure time: 22 Weeks
Target Organs: Central nervous system

Carbidopa:
Species: Rat
LOAEL: 25 mg/kg
Application Route: Oral
Exposure time: 96 Weeks
Remarks: No significant adverse effects were reported

Species: Monkey
NOAEL: 135 mg/kg
Application Route: Oral
Exposure time: 1 yr
Remarks: No significant adverse effects were reported

Species: Dog
NOAEL: 5 mg/kg
LOAEL: 15 mg/kg
Application Route: Oral
Exposure time: 238 d
Symptoms: Diarrhoea, Vomiting, Tremors

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Levodopa:
Ingestion: Symptoms: Nausea, central nervous system effects, Drowsiness

Carbidopa:
Ingestion: Symptoms: involuntary movement

SECTION 12: Ecological information

12.1 Toxicity

Components:

Levodopa:
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 16 mg/l
Exposure time: 48 h

Carbidopa:
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 35.3 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential

Components:

Levodopa:
Partition coefficient: n-octanol/water: log Pow: -2.39

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

Product:
Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product:
Endocrine disrupting potential: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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.

SECTION 14: Transport information

14.1 UN number
Not regulated as a dangerous good
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
REACH - List of substances subject to authorisation (Annex XIV): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined
15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-statements

H302: Harmful if swallowed.
H361d: Suspected of damaging the unborn child.
H372: Causes damage to organs through prolonged or repeated exposure if swallowed.
H412: Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.: Acute toxicity
Aquatic Chronic: Long-term (chronic) aquatic hazard
Repr.: Reproductive toxicity
STOT RE: Specific target organ toxicity - repeated exposure
GB EH40: UK EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA: Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL: Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation 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; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet;
**SAFETY DATA SHEET**
according to Regulation (EC) No. 1907/2006

**Carbidopa / Levodopa Formulation**

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SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

**Further information**
Sources of key data used to compile the Safety Data Sheet:

**Classification of the mixture:**

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<th>Acute Tox. 4</th>
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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

GB / EN