

according to GB/T 16483 and GB/T 17519

Carbidopa / Levodopa Formulation

| Versic 4.11 | | evision Date: 020/10/10 | | S Number: 13-00016 | Date of last issue: 2020/03/23 Date of first issue: 2015/01/23 | | |
|----------------|---|----------------------------|----|--|---|--|--|
| 1. PR | 1. PRODUCT AND COMPANY IDENTIFICATION | | | | | | |
| P | Product name | | : | Carbidopa / Levodopa Formulation | | | |
| N | Manufacturer or supplier's details | | | | | | |
| C | Company | | : | Organon & Co. | | | |
| A | Address | | : | 30 Hudson Street, 33nd floor Jersey City, New Jersey, U.S.A 07302 | | | |
| Т | Telephone | | : | 551-430-6000 | | | |
| E | Emergency telephone number | | r: | 215-631-6999 | | | |
| E | E-mail address | | : | EHSSTEWARD | ⊉organon.com | | |
| R | Recommended use of the chemical and restrictions on use | | | | | | |

: Pharmaceutical

2. HAZARDS IDENTIFICATION

Recommended use

Emergency Overview

| Appearance | : powder |
|------------|--|
| Colour | : No data available |
| Odour | : odourless |
| | Suspected of damaging the unborn child. Causes damage to organs epeated exposure. Harmful to aquatic life with long lasting effects. |

GHS Classification

| Acute toxicity (Oral) | : | Category 4 |
|--|---|------------|
| Reproductive toxicity | : | Category 2 |
| Specific target organ toxicity - repeated exposure | : | Category 1 |
| Short-term (acute) aquatic hazard | : | Category 3 |
| Long-term (chronic) aquatic hazard | : | Category 3 |
| GHS label elements Hazard pictograms | : | |

:

Signal word



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|-----------------|--|---|---|
| Hazar | d statements | H372 Causes of exposure. | if swallowed. ted of damaging the unborn child. damage to organs through prolonged or repeated to aquatic life with long lasting effects. |
| Preca | utionary statements | P202 Do not ha and understood P260 Do not bi P264 Wash ski P270 Do not ea P273 Avoid rel | reathe dust. in thoroughly after handling. at, drink or smoke when using this product. ease to the environment. otective gloves/ protective clothing/ eye protec- |
| | | CENTER/ doct | P330 IF SWALLOWED: Call a POISON or if you feel unwell. Rinse mouth. F exposed or concerned: Get medical advice/ |
| | | Storage: P405 Store loc | ked up. |
| | | Disposal: P501 Dispose disposal plant. | of contents/ container to an approved waste |
| - | cal and chemical haz assified based on avail | | |
| Harmf | n hazards ful if swallowed. Suspec gh prolonged or repeate | | unborn child. Causes damage to organs |

Environmental hazards

Harmful to aquatic life. Harmful to aquatic life with long lasting effects.

Other hazards which do not result in classification

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---------------|------------|-----------------------|
| Levodopa | 59-92-7 | >= 70 -< 90 |
| Carbidopa | 38821-49-7 | >= 10 -< 20 |
| Cellulose | 9004-34-6 | >= 1 -< 10 |

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|---|---|--|--|---|--|--|--|
| Star | ch | | 9005-25-8 | >= 1 -< 10 | | | |
| Мад | gnesium stearate | | 557-04-0 | >= 1 -< 10 | | | |
| 4. FIRST | AID MEASURES | | | | | | |
| Ger | neral advice | vice imme | diately. | el unwell, seek medical ad- ases of doubt seek medical | | | |
| If in | haled | | remove to fresh air. | | | | |
| In case of skin contact | | : In case of of water. Remove co Get medica Wash cloth | Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. | | | | |
| In c | ase of eye contact | : If in eyes, | Thoroughly clean shoes before reuse. If in eyes, rinse well with water. Get medical attention if irritation develops and persists. | | | | |
| lf sv | vallowed | : If swallowe Get medica Rinse mou | If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. | | | | |
| Most important symptoms and effects, both acute and delayed | | : Harmful if s Suspected Causes da exposure. Contact wi the skin. | swallowed. of damaging the unborn mage to organs through th dust can cause mech | n child. n prolonged or repeated anical irritation or drying of | | | |
| Prot | ection of first-aiders | : First Aid re and use th | Dust contact with the eyes can lead to mechanical irritation. 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). | | | | |
| Note | es to physician | | Treat symptomatically and supportively. | | | | |
| 5. FIREF | IGHTING MEASURES | | | | | | |
| | able extinguishing media uitable extinguishing | | sistant foam oxide (CO2) cal | | | | |
| med | | | | spersed in air in sufficient | | | |
| fight | - | concentrat potential d | ions, and in the presenc ust explosion hazard. | may be a hazard to health. | | | |
| Haz ucts | ardous combustion prod- | : Carbon ox Metal oxide | | | | | |
| Spe | cific extinguishing meth- | : Use exting | uishing measures that a | are appropriate to local cir- | | | |
| | | | | | | | |



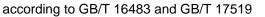


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| ods Special protective equipment for firefighters | | : | cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to so. Evacuate area. In the event of fire, wear self-contained breathing apparatus Use personal protective equipment. | | |
| 6. ACCII | DENTAL RELEASE MEAS | SUF | RES | | |
| tive | Personal precautions, protec- tive equipment and emer- gency procedures | | Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8). | | |
| Env | Environmental precautions | | Retain and dispos | akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages | |
| | Methods and materials for containment and cleaning up | | tainer for disposal Avoid dispersal of with compressed Dust deposits sho es, as these may leased into the att Local or national to posal of this mate employed in the c mine which regula Sections 13 and 1 | dust in the air (i.e., clearing dust surfaces | |

7. HANDLING AND STORAGE

| 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. |
|-------------------------|--|
| | 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 as- sessment |
| | Minimize dust generation and accumulation. |
| | Keep container closed when not in use. |
| | Keep away from heat and sources of ignition. |
| | Roop away nom noat and boarboo or ignition. |





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| Avoid | dance of contact | 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. Oxidizing agents | | |
| Stor | age | | | |
| Conditions for safe storage | | Store locke | perly labelled containers. d up. cordance with the particular national regulations. | |
| Materials to avoid | | : Do not store | e with the following product types: izing agents | |
| Packaging material | | : Unsuitable | material: None known. | |

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parame- ters / Permissible concentration | Basis |
|--------------------|------------|--|--|----------|
| Levodopa | 59-92-7 | TWA | 500 µg/m3 (OEB 2) | Internal |
| Carbidopa | 38821-49-7 | TWA | 2,000 μg/m3 (OEB 1) | Internal |
| Cellulose | 9004-34-6 | PC-TWA | 10 mg/m3 | CN OEL |
| | | TWA | 10 mg/m3 | ACGIH |
| Starch | 9005-25-8 | TWA | 10 mg/m3 | ACGIH |
| Magnesium stearate | 557-04-0 | TWA (Inhal- able particu- late matter) | 10 mg/m3 | ACGIH |
| | | TWA (Res- pirable par- ticulate mat- ter) | 3 mg/m3 | ACGIH |

| 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 equipmen | t |
| Respiratory protection : | If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. |
| 51 | Particulates type |
| Eye/face 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.





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| Hand | and body protection protection aterial | : Work uniform : Chemical-resi | or laboratory coat. stant gloves |
| Hygie | ne measures | eye flushing s ing place. When using d Wash contam The effective engineering c appropriate de industrial hygi | chemical is likely during typical use, provide ystems and safety showers close to the work- o not eat, drink or smoke. inated clothing before re-use. operation of a facility should include review of ontrols, proper personal protective equipment, egowning and decontamination procedures, ene monitoring, medical surveillance and the strative controls. |

9. PHYSICAL AND CHEMICAL PROPERTIES

| Appearance | : | powder |
|---|---|---|
| Colour | : | No data available |
| Odour | : | odourless |
| Odour Threshold | : | No data available |
| рН | : | No data available |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flash point | : | No data available |
| Evaporation rate | : | No data available |
| | | |
| Flammability (solid, gas) | : | May form explosive dust-air mixture during processing, han- dling or other means. |
| Flammability (solid, gas) Flammability (liquids) | : | |
| | : | dling or other means. |
| Flammability (liquids) Upper explosion limit / Upper | - | dling or other means. No data available |
| Flammability (liquids) Upper explosion limit / Upper flammability limit Lower explosion limit / Lower | : | dling or other means. No data available No data available |
| Flammability (liquids) Upper explosion limit / Upper flammability limit Lower explosion limit / Lower flammability limit | : | dling or other means. No data available No data available No data available |
| Flammability (liquids) Upper explosion limit / Upper flammability limit Lower explosion limit / Lower flammability limit Vapour pressure | : | dling or other means. No data available No data available No data available No data available |

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|--|---|---|
| Solubility(ies) Water solubility Partition coefficient: n- octanol/water Auto-ignition temperature | No data available No data available No data available | 2 |
| Decomposition temperature | : No data available | 9 |
| Viscosity Viscosity, dynamic Viscosity, kinematic | : No data available : No data available | |
| Explosive properties | : Not explosive | |
| Oxidizing properties Molecular weight | : The substance of : No data available | r mixture is not classified as oxidizing. |
| Particle size | : No data available |) |

10. STABILITY AND REACTIVITY

| Reactivity Chemical stability Possibility of hazardous reac- tions | : | Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents. |
|---|---|--|
| Conditions to avoid | : | Heat, flames and sparks. Avoid dust formation. |
| Incompatible materials | : | |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

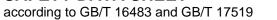
11. TOXICOLOGICAL INFORMATION

| Exposure routes | - | Inhalation Skin contact Ingestion Eye contact |
|---|---|--|
| Acute toxicity Harmful if swallowed. | | |
| <u>Product:</u> Acute oral toxicity | | Acute toxicity estimate: 1,952 mg/kg Method: Calculation method |

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|----------------|------------------------------|---------------|--|--|
| <u>Com</u> | oonents: | | | |
| Levo | dopa: | | | |
| | oral toxicity | : L[| D50 (Rat): 1, | 780 mg/kg |
| | | L | D50 (Mouse) |): 2,363 mg/kg |
| Carbi | dopa: | | | |
| Acute | oral toxicity | : L[| D50 (Rat): 4, | ,810 mg/kg |
| | | L | D50 (Mouse) |): 1,750 mg/kg |
| Cellu | lose: | | | |
| Acute | oral toxicity | : LI | 050 (Rat): > | 5,000 mg/kg |
| Acute | inhalation toxicity | E | C50 (Rat): > xposure time est atmosphe | |
| Acute | e dermal toxicity | : L[| 050 (Rabbit) | : > 2,000 mg/kg |
| Starc | h: | | | |
| Acute | oral toxicity | : L[| 050 (Rat): > | 5,000 mg/kg |
| Acute | e dermal toxicity | : L(| 050 (Rabbit) | : > 2,000 mg/kg |
| Magn | esium stearate: | | | |
| Acute | oral toxicity | M A: ic | ethod: OEC ssessment: | 2,000 mg/kg D Test Guideline 423 The substance or mixture has no acute oral to sed on data from similar materials |
| Acute | e dermal toxicity | | | : > 2,000 mg/kg sed on data from similar materials |
| Skin | corrosion/irritation | | | |
| Not cl | assified based on av | ailable info | ormation. | |
| <u>Com</u> | <u>ponents:</u> | | | |
| | dopa: | | | |
| Speci Resul | | | abbit o skin irritati | on |
| Magn | esium stearate: | | | |
| Speci | | | abbit | |
| Resul Rema | | | o skin irritati ased on data | on a from similar materials |
| . come | | . D | | |
| | | | | |





| sion 1 | Revision Date: 2020/10/10 | SDS Number: 50113-00016 | Date of last issue: 2020/03/23 Date of first issue: 2015/01/23 |
|---|--|--|---|
| Serio | us eye damage/eye | irritation | |
| Not cl | assified based on ava | ailable information. | |
| <u>Comp</u> | oonents: | | |
| Carbi | dopa: | | |
| Speci | - | : Rabbit | |
| Resul | | : Mild eye irritation | on |
| Starc | h: | | |
| Speci | es | : Rabbit | |
| Resul | | : No eye irritation | n |
| Magn | esium stearate: | | |
| Speci | | : Rabbit | |
| Resul | | : No eye irritation | |
| Rema | urks | : Based on data | from similar materials |
| Respi | iratory or skin sensi | itisation | |
| Skin s | sensitisation | | |
| Not cl | assified based on ava | ailable information. | |
| Deen | iratory sensitisation | | |
| Resp | | | |
| - | - | | |
| Not cl | assified based on ava | | |
| Not cl | assified based on ava <u> ponents:</u> | | |
| Not cl Comp Levoo | assified based on ava ponents: dopa: | ailable information. | |
| Not cl | assified based on ava ponents: dopa: es | | sitizer. |
| Not cl Comp Levou Speci Resul | assified based on ava ponents: dopa: es | ailable information. : Guinea pig | sitizer. |
| Not cl Comp Levou Speci Resul | assified based on ava <u>ponents:</u> dopa: es t dopa: | ailable information. : Guinea pig | |
| Not cl Comp Levod Specia Resul Carbi | assified based on ava <u>ponents:</u> dopa: es t dopa: urks | ailable information. : Guinea pig : Not a skin sens | |
| Not cl <u>Comp</u> Levoo Speci Resul Carbi Rema Starc | assified based on ava <u>conents:</u> dopa: t dopa: urks h: | ailable information. : Guinea pig : Not a skin sens : No data availal | ble |
| Not cl <u>Comp</u> Levoo Speci Resul Carbi Rema Starc Test T | assified based on ava <u>conents:</u> dopa: t dopa: urks h: Fype | ailable information. : Guinea pig : Not a skin sens | ble |
| Not cl <u>Comr</u> Levod Speci Resul Carbi Rema Starc Test T Expos Speci | assified based on ava <u>ponents:</u> dopa: es t dopa: urks h: Fype sure routes es | ailable information. : Guinea pig : Not a skin sens : No data availal : Maximisation T : Skin contact : Guinea pig | ble |
| Not cl <u>Comp</u> Levoo Speci Resul Carbi Rema Starc Test T Expos | assified based on ava <u>ponents:</u> dopa: es t dopa: urks h: Fype sure routes es | ailable information. : Guinea pig : Not a skin sens : No data availal : Maximisation T : Skin contact | ble |
| Not cl <u>Comp</u> Levoo Speci Resul Carbi Rema Starc Test T Expos Speci Resul | assified based on ava <u>ponents:</u> dopa: es t dopa: urks h: Fype sure routes es | ailable information. : Guinea pig : Not a skin sens : No data availal : Maximisation T : Skin contact : Guinea pig | ble |
| Not cl <u>Comp</u> Levod Specia Resul Carbi Rema Starc Test T Expos Specia Resul Magn Test T | assified based on ava <u>conents:</u> dopa: es t dopa: urks h: Type sure routes es t t esium stearate: Type | ailable information. : Guinea pig : Not a skin sens : No data availal : Maximisation T : Skin contact : Guinea pig | ble Test |
| Not cl <u>Comp</u> Levod Specia Resul Carbi Rema Starc Test 1 Expos Specia Resul Magn Test 1 Expos | assified based on ava <u>conents:</u> dopa: es t dopa: urks h: Type sure routes es t t esium stearate: Type sure routes | ailable information. : Guinea pig : Not a skin sens : No data availal : Maximisation T : Skin contact : Guinea pig : negative : Maximisation T : Skin contact | ble Test |
| Not cl <u>Comp</u> Levoo Speci Resul Carbi Rema Starc Test T Expos Speci Resul Magn Test T Expos Speci | assified based on ava <u>conents:</u> dopa: es t dopa: urks h: Fype sure routes es t esium stearate: Fype sure routes es | ailable information. : Guinea pig : Not a skin sens : No data availal : Maximisation T : Skin contact : Guinea pig : negative : Maximisation T : Skin contact : Guinea pig | ole ēst |
| Not cl <u>Comp</u> Levoo Speci Resul Carbi Rema Starc Test T Expos Speci Resul Magn Test T Expos Speci Method | assified based on ava <u>conents:</u> dopa: es t dopa: urks h: Type sure routes es t esium stearate: Type sure routes es od | ailable information. : Guinea pig : Not a skin sens : No data availal : Maximisation T : Skin contact : Guinea pig : negative : Maximisation T : Skin contact : Guinea pig : OECD Test Gu | ole ēst |
| Not cl <u>Comp</u> Levoo Speci Resul Carbi Rema Starc Test T Expos Speci Resul Magn Test T Expos Speci | assified based on ava <u>conents:</u> dopa: es t dopa: urks h: Fype sure routes es t esium stearate: Fype sure routes es t fype sure routes es t | ailable information. : Guinea pig : Not a skin sens : No data availal : Maximisation T : Skin contact : Guinea pig : negative : Maximisation T : Skin contact : Guinea pig : OECD Test Gu : negative | ole ēst |

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| ersion I 1 | Revision Date: 2020/10/10 | SDS Number: 50113-00016 | Date of last issue: 2020/03/23 Date of first issue: 2015/01/23 |
|---------------|--|--|---|
| | cell mutagenicity assified based on ava | ailable information. | |
| Comp | onents: | | |
| Levod | opa: | | |
| Genoto | oxicity in vitro | : Test Type: Ba Result: negat | acterial reverse mutation assay (AMES) ive |
| | | | nromosomal aberration mouse lymphoma cells ocal |
| | | | icronucleus test Chinese hamster lung cells /e |
| | | | ster chromatid exchange assay Chinese hamster lung cells /e |
| Carbid | lopa: | | |
| Genoto | oxicity in vitro | : Test Type: Ba Result: positiv | acterial reverse mutation assay (AMES) /e |
| | | Test Type: In Result: positiv | vitro mammalian cell gene mutation test /e |
| Genoto | oxicity in vivo | : Test Type: M Species: Mou Application R Result: negat | oute: Oral |
| Cellulo | ose: | | |
| Genoto | oxicity in vitro | : Test Type: Ba Result: negat | acterial reverse mutation assay (AMES) ive |
| | | Test Type: In Result: negat | vitro mammalian cell gene mutation test ive |
| Genoto | oxicity in vivo | cytogenetic a Species: Mou | se oute: Ingestion |
| Starch | | | |
| - | oxicity in vitro | : Test Type: Ba Result: negat | acterial reverse mutation assay (AMES) |

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|----------------|--|--------|---|---|
| Geno | Genotoxicity in vitro | | Result: negative | tro mammalian cell gene mutation test e d on data from similar materials |
| | | | Method: OECD Result: negative | omosome aberration test in vitro Test Guideline 473 e d on data from similar materials |
| | | | Result: negative | terial reverse mutation assay (AMES) e d on data from similar materials |
| | nogenicity lassified based on avai | ilable | information. | |
| Com | oonents: | | | |
| Levo | dopa: | | | |
| | cation Route sure time | :: | Rat Oral 2 Years negative | |
| Carbi | idopa: | | | |
| | cation Route sure time | : | Rat Oral 96 weeks 135 mg/kg body negative | y weight |
| • • | | | - | |
| | es cation Route sure time | : | Rat Ingestion 72 weeks negative | |
| - | oductive toxicity ected of damaging the | unbo | rn child. | |
| <u>Com</u> | oonents: | | | |
| Levo | dopa: | | | |
| Effect | ts on fertility | : | | |
| Effect ment | ts on foetal develop- | : | Test Type: Dev Species: Rabbi Application Rou | t |
| | | | | |

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| | | | tal Toxicity: LOAEL: 125 mg/kg body weight Skeletal malformations, Visceral malformations ve |
| | | Test Type: D Species: Rat Application R Development | |
| | | | use coute: Oral tal Toxicity: LOAEL: 500 mg/kg body weight ffects on foetal development |
| Repro sessm | ductive toxicity - As- nent | : Some eviden animal exper | ce of adverse effects on development, based or iments. |
| Carbi | dopa: | | |
| Effects | s on fertility | Symptoms: R | |
| Effect: ment | s on foetal develop- | | JSE |
| | | | bbit |
| Cellul | ose: | | |
| Effects | s on fertility | Species: Rat | oute: Ingestion |
| Effects ment | s on foetal develop- | Species: Rat | coute: Ingestion |
| Magn | esium stearate: | | |
| Effects | s on fertility | : Test Type: C | ombined repeated dose toxicity study with the |

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| | | S A N R | pecies: Rat pplication Route lethod: OECD T esult: negative | elopmental toxicity screening test e: Ingestion est Guideline 422 on data from similar materials |
| Effect ment | s on foetal develop- | S A R | pecies: Rat pplication Route esult: negative | yo-foetal development e: Ingestion on data from similar materials |

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 LOAEL Application Route Exposure time Target Organs Symptoms | Rat 100 mg/kg Oral 106 Weeks Central nervous system Salivation |
|---|---|
| Species LOAEL Application Route Exposure time Target Organs | Monkey 100 mg/kg Oral 22 Weeks Central nervous system |
| Carbidopa: | |
| Species LOAEL Application Route Exposure time Remarks | Rat 25 mg/kg Oral 96 Weeks No significant adverse effects were reported |
| O | NA-mlan. |

Species

: Monkey

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|-------------------------|--|--|---|
| | cation Route sure time | : 135 mg/kg : Oral : 1 yr : No significant | adverse effects were reported |
| | EL EL cation Route sure time | : Dog : 5 mg/kg : 15 mg/kg : Oral : 238 d : Diarrhoea, Vo | omiting, Tremors |
| | es | : Rat : >= 9,000 mg/ł : Ingestion : 90 Days | <g< td=""></g<> |
| | es EL cation Route sure time | : Rat : >= 2,000 mg/l : Skin contact : 28 Days : OECD Test G | |
| Speci NOAE Applic | EL cation Route sure time | : Rat : > 100 mg/kg : Ingestion : 90 Days : Based on data | a from similar materials |
| Not cl | ation toxicity assified based on ava rience with human e | | |
| - | oonents: | | |
| Levo Inges | dopa: | : Symptoms: N | ausea, central nervous system effects, Drowsi- |
| - | dopa: | ness | voluntary movement |

according to GB/T 16483 and GB/T 17519



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|-----------------|--|---|---|--|
| 40.500 | | | | |
| 12. ECO | LOGICAL INFORMATION | N | | |
| Eco | toxicity | | | |
| <u>Cor</u> | nponents: | | | |
| Lev | odopa: | | | |
| | icity to daphnia and other atic invertebrates | : | EC50 (Daphnia m Exposure time: 48 | agna (Water flea)): 16 mg/l 3 h |
| Car | bidopa: | | | |
| | icity to daphnia and other atic invertebrates | : | EC50 (Daphnia m Exposure time: 48 Method: OECD Te | |
| Cell | ulose: | | | |
| Тох | icity to fish | : | Exposure time: 48 | ipes (Japanese medaka)): > 100 mg/l 3 h on data from similar materials |
| Мас | gnesium stearate: | | | |
| - | icity to fish | : | Exposure time: 48 Method: DIN 384 | |
| | icity to daphnia and other atic invertebrates | : | Exposure time: 47 Test substance: V Method: Directive | Vater Accommodated Fraction 67/548/EEC, Annex V, C.2. on data from similar materials |
| Tox plar | icity to algae/aquatic its | : | mg/l Exposure time: 72 Test substance: V Method: OECD Te | Vater Accommodated Fraction est Guideline 201 on data from similar materials |
| | | | mg/l Exposure time: 72 Test substance: V Method: OECD Te | Vater Accommodated Fraction |
| Тох | icity to microorganisms | : | Exposure time: 16 | nas putida): > 100 mg/l 5 h Vater Accommodated Fraction |

according to GB/T 16483 and GB/T 17519



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| | | | Remarks: Base | ed on data from similar materials |
| Persi | stence and degradab | oility | | |
| <u>Comp</u> | oonents: | | | |
| Cellul Biode | lose: gradability | : | Result: Readily | biodegradable. |
| - | esium stearate: gradability | : | | degradable ed on data from similar materials |
| Bioac | cumulative potential | I | | |
| <u>Comp</u> | oonents: | | | |
| | dopa: on coefficient: n- ol/water | : | log Pow: -2.39 | |
| Partiti | esium stearate: on coefficient: n- ol/water | : | log Pow: > 4 | |
| Mobil | ity in soil | | | |
| No da | ta available | | | |
| Other | adverse effects | | | |
| No da | ita available | | | |

Disposal methods

| Waste from residues Contaminated packaging | : | Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. |
|---|---|--|
|---|---|--|

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

according to GB/T 16483 and GB/T 17519



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National Regulations

GB 6944/12268

Not regulated as a dangerous good

Special precautions for user Not applicable

15. REGULATORY INFORMATION

National regulatory information Law on the Prevention and Control of Occupational Diseases

The components of this product are reported in the following inventories:

| AICS | : | not determined |
|-------|---|----------------|
| DSL | : | not determined |
| IECSC | : | not determined |

16. OTHER INFORMATION

| Further information | | | | |
|---|--|--|--|--|
| Sources of key data used to : compile the Safety Data Sheet | Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/ | | | |
| Date format : | yyyy/mm/dd | | | |
| Full text of other abbreviations | | | | |
| ACGIH : | USA. ACGIH Threshold Limit Values (TLV) | | | |
| CN OEL : | Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents. | | | |
| | 8-hour, time-weighted average | | | |
| CN OEL / PC-TWA : | Permissible concentration - time weighted average | | | |

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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 Con-



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centration 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Disclaimer

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.

CN / EN