

SECTION 1: Identification

1.1. Identification

Product form : Mixture
 Product name : Inbrija

1.2. Recommended use and restrictions on use

Recommended use : Drug

1.3. Supplier

Manufacturer

Merz Therapeutics GmbH
 100 Eckenheimer Landstr.
 Frankfurt/Main, 60318
 Germany
 T + 49 - 34 901 - 88 58 - 0 - F + 49 - 34 901 - 88 58 - 9
HSSE@merz.de - www.merz.de

Importer

Cardinal Health
 501 Mason Rd, Suite 200
 LaVergne, TN 37086
 USA
 T +1-615-280-4286

E-mail address of competent person responsible for the SDS: sds@gbk-ingelheim.de

1.4. Emergency telephone number

Emergency number : 1-800-367-5109

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Acute toxicity (oral) Category 4	H302	Harmful if swallowed
Skin corrosion/irritation Category 2	H315	Causes skin irritation
Serious eye damage/eye irritation Category 2	H319	Causes serious eye irritation.
Carcinogenicity Category 2	H351	Suspected of causing cancer
Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation	H335	May cause respiratory irritation.

Full text of H statements : see section 16

2.2. GHS Label elements, including precautionary statements

GHS US labeling

Hazard pictograms (GHS US) :



Signal word (GHS US) : Warning

Hazard statements (GHS US) : H302 - Harmful if swallowed
 H315 - Causes skin irritation
 H319 - Causes serious eye irritation.
 H335 - May cause respiratory irritation.
 H351 - Suspected of causing cancer

Precautionary statements (GHS US) : P201 - Obtain special instructions before use.
 P202 - Do not handle until all safety precautions have been read and understood.
 P261 - Avoid breathing dust.

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P264 - Wash hands, forearms and face thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P271 - Use only outdoors or in a well-ventilated area.
P280 - Wear eye protection, face protection, protective gloves.
P301+P312 - If swallowed: Call a POISON CENTER, a doctor if you feel unwell.
P302+P352 - If on skin: Wash with plenty of soap and water.
P304+P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P312 - Call a POISON CENTER, a doctor if you feel unwell.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P330 - Rinse mouth.
P332+P313 - If skin irritation occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P403+P233 - Store in a well-ventilated place. Keep container tightly closed.
P405 - Store locked up
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

No additional information available

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS US classification
Levodopa	CAS-No.: 59-92-7	≥ 40 – < 45	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
Titanium dioxide	CAS-No.: 13463-67-7	≥ 0.5 – < 1	Carc. 2, H351

Specific concentration limits:

Name	Product identifier	Specific concentration limits (%)
ammonium hydroxide	CAS-No.: 1336-21-6	(5 ≤ C ≤ 100) STOT SE 3; H335

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures

First-aid measures general : Call a poison center/doctor/physician if you feel unwell.

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First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor/physician if you feel unwell.
First-aid measures after skin contact	: Wash skin with plenty of water. Take off contaminated clothing. If skin irritation occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Rinse mouth. Call a poison center/doctor/physician if you feel unwell.

4.2. Most important symptoms and effects (acute and delayed)

Symptoms/effects after inhalation	: If dust are formed : May cause respiratory irritation.
Symptoms/effects after skin contact	: Irritation.
Symptoms/effects after eye contact	: Dust from this product may cause eye irritation. Eye irritation.
Symptoms/effects after ingestion	: Harmful if swallowed.
Chronic symptoms	: Suspected of causing cancer.

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media	: Water spray. Dry powder. Foam.
Unsuitable extinguishing media	: Do not use a solid water stream as it may scatter and spread fire.

5.2. Specific hazards arising from the chemical

Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: Toxic fumes may be released.

5.3. Special protective equipment and precautions for fire-fighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Avoid contact with eyes, skin or mucous membrane. Evacuate the danger area. Evacuate personnel to a safe area.
6.1.1. For non-emergency personnel	
Emergency procedures	: Ventilate spillage area. Avoid breathing spray, mist, dust. Avoid contact with skin and eyes.
6.1.2. For emergency responders	
Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Mechanically recover the product.
Other information	: Dispose of materials or solid residues at an authorized site.

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6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed	: Avoid creating or spreading dust. Do not breathe dust.
Precautions for safe handling	: Use only outdoors or in a well-ventilated area. Avoid breathing spray, mist, dust. Avoid contact with skin and eyes. Wear personal protective equipment.
Hygiene measures	: Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store locked up. Store in a well-ventilated place. Keep container tightly closed. Keep cool.
Information on mixed storage	: Keep away from food, drink and animal feeding stuffs.
Storage area	: Protect from moisture. Store away from direct sunlight or other heat sources.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Titanium dioxide (13463-67-7)	
USA - ACGIH - Occupational Exposure Limits	
Local name	Titanium dioxide
ACGIH OEL TWA	0.2 mg/m ³ (Nanoscale particles. R - Repairable particulate matter) 2.5 mg/m ³ (Finescale particles. R - Repairable particulate matter)
Remark (ACGIH)	TLV® Basis: LRT irr; pneumoconiosis. Notations: A3 (Confirmed Animal Carcinogen with Unknown Relevance to Humans)
Regulatory reference	ACGIH 2024
USA - OSHA - Occupational Exposure Limits	
Local name	Titanium dioxide (Total dust)
OSHA PEL TWA	15 mg/m ³
Regulatory reference (US-OSHA)	OSHA Annotated Table Z-1

8.2. Appropriate engineering controls

Appropriate engineering controls	: Ensure good ventilation of the work station.
Environmental exposure controls	: Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Hand protection:

Use protective gloves in the event of intensive contact

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Type	Material	Permeation	Thickness (mm)	Penetration
Chemically resistant protective gloves, Disposable gloves	Nitrile rubber (NBR), Chloroprene rubber (CR), butyl rubber	6 (> 480 minutes)	≥ 0,4	

Eye protection:

In case of dust production: protective goggles. Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

Dust production: dust mask with filter type P2

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: capsules.
Color	: White Black
Odor	: odorless
Odor threshold	: No data available
pH	: No data available
Melting point	: 285 °C
Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: Non flammable.
Vapor pressure	: ≈ 0 hPa (20 °C)
Relative vapor density at 20°C	: No data available
Relative density	: No data available
Solubility	: Water: Slightly soluble
Log Pow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: Not applicable
Explosion limits	: Not applicable
Explosive properties	: Product is not explosive.
Oxidizing properties	: Non oxidizing material.

9.2. Other information

VOC content : ≤ 3 %

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

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10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

Strong acids, strong bases and oxidation agents.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Harmful if swallowed.
Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

Inbrija	
ATE US (oral)	1190.476 mg/kg body weight
Levodopa (59-92-7)	
ATE US (oral)	500 mg/kg body weight
Titanium dioxide (13463-67-7)	
ATE US (oral)	5000 mg/kg body weight

Skin corrosion/irritation : Causes skin irritation.
Serious eye damage/irritation : Causes serious eye irritation.
Respiratory or skin sensitization : Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity : Suspected of causing cancer.

Titanium dioxide (13463-67-7)	
IARC group	2B - Possibly carcinogenic to humans

Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure : May cause respiratory irritation.
STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)
Viscosity, kinematic : No data available
Symptoms/effects after inhalation : If dust are formed : May cause respiratory irritation.
Symptoms/effects after skin contact : Irritation.
Symptoms/effects after eye contact : Dust from this product may cause eye irritation. Eye irritation.
Symptoms/effects after ingestion : Harmful if swallowed.
Chronic symptoms : Suspected of causing cancer.

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SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with DOT / IMDG / IATA

DOT	IMDG	IATA
14.1. UN number		
Not regulated for transport		
14.2. Proper Shipping Name		
Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)		
Not regulated	Not regulated	Not regulated
14.4. Packing group		
Not regulated	Not regulated	Not regulated
14.5. Environmental hazards		
Not regulated	Not regulated	Not regulated
No supplementary information available		

14.6. Special precautions for user

DOT

Not regulated

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IMDG

Not regulated

IATA

Not regulated

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

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

15.2. International regulations

No additional information available

15.3. US State regulations



WARNING:

This product can expose you to chemicals including Titanium dioxide (airborne, unbound particles of respirable size), which is known to the State of California to cause cancer, and Levodopa, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

SECTION 16: Other information

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Other information

: Data of sections 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities. The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge. The delivery specifications are contained in the corresponding product sheet. This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

Full text of H-phrases	
H302	Harmful if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H351	Suspected of causing cancer

Abbreviations and acronyms	
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
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor

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Abbreviations and acronyms	
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disruptor
DOT	Department of Transport
TDG	Transportation of Dangerous Goods
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals

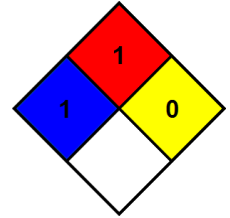
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Abbreviations and acronyms	
IBC-Code	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
MARPOL 73/78	MARPOL 73/78: International Convention for the Prevention of Pollution From Ships
ADG	Transport of Australian Dangerous Goods

NFPA health hazard : 1 - Materials that, under emergency conditions, can cause significant irritation.
NFPA fire hazard : 1 - Materials that must be preheated before ignition can occur.
NFPA reactivity : 0 - Material that in themselves are normally stable, even under fire conditions.



Hazard Rating
Health : 3 Serious Hazard - Major injury likely unless prompt action is taken and medical treatment is given
: * - Chronic (long-term) health effects may result from repeated overexposure
Flammability : 1 Slight Hazard - Materials that must be preheated before ignition will occur. Includes liquids, solids and semi solids having a flash point above 200 F. (Class IIIB)
Physical : 0 Minimal Hazard - Materials that are normally stable, even under fire conditions, and will NOT react with water, polymerize, decompose, condense, or self-react. Non-Explosives.
Personal protection : E - Safety glasses, Gloves, Dust respirator

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should therefore not be construed as guaranteeing any specific property of the product.