

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING**GHS product identifier**

Product Name BOTOX® (Botulinum Toxin Type A) Purified Neurotoxin Complex (50, 100 and 200 Units) BOTOX® Cosmetic (Botulinum Toxin Type A) Purified Neurotoxin Complex (50, 100 and 200 Units)

Other means of identification

Synonyms onabotulinumtoxinA

Recommended use of the chemical and restrictions on use

Recommended Use No information available

Uses advised against No information available

Supplier's details**Supplier Address**

Allergan, Inc.
2525 Dupont
Irvine, CA
TEL: 1-714-246-4500

Emergency telephone number

Emergency Telephone Number Chemtrec 1-800-424-9300

2. HAZARDS IDENTIFICATION**Classification**

Reproductive Toxicity

Category 2

GHS Label elements, including precautionary statements**Emergency Overview****Signal Word****Warning****Hazard Statements**

- Suspected of damaging fertility or the unborn child



Appearance White Dehydrated Product **Physical State** Solid.

Odor None

Precautionary Statements

Prevention

- Obtain special instructions before use.
- Do not handle until all safety precautions have been read and understood.
- Use personal protective equipment as required.

General Advice

- If exposed or concerned: Get medical attention/advice

Storage

- Store locked up.

Disposal

- Dispose of contents/container to an approved waste disposal plant.

Hazard Not Otherwise Classified (HNOC)

Not applicable

Other information

None known

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %	Trade secret
Botulinum Toxin Type A	93384-43-1	<0.002	*

* Where range is displayed, the exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of necessary first-aid measures

Eye Contact	Immediate medical attention is required. Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes.
Skin Contact	Wash skin with soap and water. Launder clothing before re-use.
Inhalation	Move to fresh air and seek medical attention.
Ingestion	Immediate medical attention is required. If the toxin is ingested, induce vomiting or aspirate stomach contents as soon as possible in a hospital emergency room.
Protection of First-aiders	Do not use mouth-to-mouth method if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms/effects, acute and delayed

Most Important Symptoms/Effects Difficulty in breathing. Coughing and/ or wheezing. Respiratory failure.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media None.

Specific Hazards Arising from the Chemical

None known

Explosion Data

Sensitivity to Mechanical Impact

None.

Sensitivity to Static Discharge

None.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions

Evacuate personnel to safe areas. Ensure trained personnel conduct clean up. Do not touch or walk through spilled material. Do not get in eyes, on skin, or on clothing. Wear appropriate protective clothing.

Environmental Precautions

Environmental Precautions

See Section 12 for additional Ecological Information.

Methods and materials for containment and cleaning up

Methods for Containment

During normal patient use, any spilled material should be wiped up and the waste disposed of as medical waste. For large quantity releases, such as at manufacturing or distribution centers, contain the spill and neutralize all contaminated services and equipment using either sodium hypochlorite or autoclaving.

Methods for Cleaning Up

Sodium hypochlorite in concentrations of 0.5% or greater (equivalent to a 1:10 dilution of household bleach) may be used to bathe all surfaces exposed to botulinum toxin for a period of ten minutes. Following this, the product is rendered safe and the materials may be disposed through standard methods. For spills onto surface areas, the contaminated surface should be thoroughly sprayed or rinsed for ten minutes with a 0.5% sodium hypochlorite solution, then wiped dry. Autoclaving may be applied to botulinum toxin contaminated material which is in solution or to which the autoclave steam has access. Autoclaving at 121 °C for 30 minutes or greater will render the product inactive

7. HANDLING AND STORAGE

Precautions for safe handling

Handling

See the product information described on the package insert for proper information on handling and storage.

Conditions for safe storage, including any incompatibilities

Storage

Do not store with food. Keep in properly labeled containers. Store according to label instructions.

Incompatible Products

None known.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering Measures Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations and safety showers are close to the workstation location.

Individual protection measures, such as personal protective equipment

Eye/Face Protection There are no engineering controls required for handling of individual vials. Suitable eye protection should be worn if there is risk to contact.

Skin and Body Protection Lightweight protective clothing. Protective gloves should be worn. Risk of needle stick injuries should be minimized. Avoid contact with broken skin

Respiratory Protection Respiratory protection should not be required under normal handling of this product.

Hygiene Measures Universal precautions as recommended by the Centers for Disease Control (CDC) should be implemented during medical procedures involving the injection of the product. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Provide regular cleaning of equipment, work area and clothing. Keep away from food, drink and animal feeding stuffs. Contaminated work clothing should not be allowed out of the workplace.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Solid	Appearance	White Dehydrated Product
Odor	None	Odor Threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks/ - Method</u>
pH	No data available	None known
Melting Point/Range	No data available	None known
Boiling Point/Boiling Range	No data available	None known
Flash Point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limits in Air		
upper flammability limit	No data available	
lower flammability limit	No data available	
Vapor Pressure	No data available	None known
Vapor Density	No data available	None known
Specific Gravity	1.1	None known
Water Solubility	Soluble in water.	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known
Autoignition Temperature	No data available	None known
Decomposition Temperature	No data available	None known
Viscosity	No data available	None known
Flammable Properties	Not flammable	
Explosive Properties	No data available	
Oxidizing Properties	No data available	

Other information

VOC Content (%) No data available

10. STABILITY AND REACTIVITY

Reactivity

Not reactive under normal conditions.

Chemical stability

Stability and biological activity of the toxin is influenced by factors such as heat, salts, acids, bases, organic solvents, physical and/or chemical environments, photooxidation, and irradiation.

Possibility of hazardous reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

None known.

Incompatible materials

None known.

Hazardous decomposition products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Contains Clostridium botulinum type A neurotoxin complex (~900kilodaltons [kD]), a potent neurotoxin. The toxin acts by blocking neuromuscular transmission from the peripheral nerves which lead to the muscles.

Inhalation

There is no data available for this product.

Eye Contact

There is no data available for this product.

Skin Contact

There is no data available for this product.

Ingestion

There is no data available for this product.

Toxicology data for the components

Botulinum Toxin type A:

Toxicity Data (RTECS): lpr; mus; LD50: 160 ng/kg TXAPA9 28:227, 1974

Scu; mus; LD50: 4 ng/kg TOXIA6 24:1065, 1986

Unr; mus; LD50: 30 pg/kg IGAYAY 112:861, 1980

Scu; rat; LDLo: 1250 mg/kg JPHYA7 260:177, 1976

It is reported that a dose of 1 microgram may be fatal to humans if swallowed or inhaled. It has been estimated that the human LD50 by injection is approximately 80 to 560 ng (equivalent to 2800 mouse units, depending on the specific potency of the toxin) for a 70 kg adult. This is equivalent to 28 (100 unit vials).

Single dose toxicity studies were conducted by intramuscular (i.m.) administration in rats, rabbits and monkeys, and by intravenous (i.v.) administration in rats. The LD50 values ranged from 50 to 57 Units per kilogram (U/kg) following i.v. injection and 71 to 143 U/kg following i.m. injection in rats. Single dose No Observed Effect Levels (NOEL) in monkeys ranged from 4 to 24 U/kg following i.m. injection.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Symptoms may occur several hours to days following exposure: muscle paralysis; difficulty in speaking; double or blurred vision; swallowing difficulties; paralysis of urinary bladder; death due to respiratory failure.

Delayed and immediate effects and also chronic effects from short and long term exposure

Sensitization No information available.
Mutagenic Effects Negative in multiple in vitro and in vivo assays.
Carcinogenicity Studies in animals have not been performed to evaluate the carcinogenic potential of BOTOX® and BOTOX® Cosmetic™. The product is not structurally related to any known carcinogens. The clinical experience with BOTOX® (Botulinum Toxin Type A) Purified Neurotoxin Complex (100 Units) since 1980 has provided no evidence of carcinogenicity. In addition, in vitro and in vivo mutagenicity and genotoxicity studies showed no carcinogenic potential.

Reproductive Toxicity In fertility studies of BOTOX, male or female rats were injected intramuscularly prior to mating and on the day of mating, reduced fertility was observed in males.

Developmental Toxicity When injected intramuscularly, the neurotoxin complex has been shown to be teratogenic or to have embryocidal effects in some animal species. Women of childbearing age should handle this product with extreme care and observe all precautionary handling information.

STOT - single exposure See listed target organs below.
STOT - repeated exposure See listed target organs below.
Target Organ Effects Musculoskeletal system. Respiratory system.
Aspiration Hazard No information available.

Numerical measures of toxicity - Product

The following values are calculated based on chapter 3.1 of the GHS document: Not applicable

12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Persistence and Degradability No information available.

Bioaccumulation No information available.

Other Adverse Effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods	All vials, including expired vials, and equipment or materials used with the drug should be disposed of according to local regulatory requirements. For disposal of multiple vials, contact Allergan for further information.
Contaminated Packaging	Do not re-use empty containers.

14. TRANSPORT INFORMATION

Note: This product is considered a 'Biological Product' for transportation purposes. The product is not regulated as a hazardous material by the US DOT, Canadian TDG, or the European Union ADR for road/ rail transportation purposes and is not regulated as a hazardous material for air transportation by IATA guidelines.

DOT	Not regulated
TDG	Not regulated.
IATA	Not regulated.

15. REGULATORY INFORMATION

<u>International Inventories</u>	
TSCA	All components of this product are either listed or are exempt on the TSCA inventory.
DSL	Substances comply or are exempt

<u>Legend</u>	
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory	
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List	

<u>U.S. Federal Regulations</u>	
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.	

<u>SARA 311/312 Hazard Categories</u>	
Acute Health Hazard	Yes
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

<u>Clean Water Act</u>	
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).	

<u>CERCLA</u>	
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.	

<u>U.S. State Regulations</u>	
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<u>California Proposition 65</u>	
This product does not contain any Proposition 65 chemicals.	

<u>U.S. State Right-to-Know Regulations</u>	
This product does not contain any substances above threshold limits that are regulated by state right-to-know.	

<u>U.S. EPA Label Information</u>	
EPA Pesticide Registration Number	Not applicable

16. OTHER INFORMATION

<u>NFPA</u>	Health Hazard	1	Flammability	0	Instability	0	Physical and Chemical Hazards	-
<u>HMIS</u>	Health Hazard	1*	Flammability	0	Physical Hazard	0	Personal Protection	X

*Indicates a chronic health hazard.

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General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet