



SAFETY DATA SHEET

Revision Date 02-Oct-2018

Version 10

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Chemical Name Kybella

Other means of identification

Product Code FG00070

Synonyms Deoxycholic Acid Belkyra

Recommended use of the chemical and restrictions on use

Recommended Use Reduction of localized SC fat deposits in the submental region

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet

Manufacturer

Allergan plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525

E-mail address SDS@Allergan.com

Emergency telephone number

Emergency Telephone

Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.122)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label elements

Emergency Overview

The product contains no substances which at their given concentration, are considered to be hazardous to health

Appearance gel

Physical state Liquid

Odor No information available

Chemical Name
Deoxycholic Acid

Symptoms

The most common adverse reactions (>20% of subjects) include injection site edema/swelling, hematoma, pain, numbness, erythema and induration.

Chemical Name

Medical Conditions Aggravated by Exposure

Deoxycholic Acid KYBELLA is contraindicated in the presence of infection at the injection sites.

Other Information

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	EINECS	Weight-%
PURIFIED WATER USP	7732-18-5	231-791-2	60 - 100*
Deoxycholic Acid	83-44-3	201-478-5	1 - 5*
Benzyl Alcohol	100-51-6	202-859-9	0.1 - 1*
SODIUM CHLORIDE USP	7647-14-5	231-598-3	0.1 - 1*
SODIUM HYDROX 1.0N SOLN	1310-73-2	215-185-5	0.1 - 1*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

First aid measures

General advice	If symptoms persist, call a physician. Do not breathe dust/fume/gas/mist/vapors/spray. Do not get in eyes, on skin, or on clothing.
Eye contact	Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. If symptoms persist, call a physician.
Skin Contact	Consult a physician if necessary. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
Inhalation	Remove to fresh air. Call a physician. If breathing is irregular or stopped, administer artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.
Ingestion	Rinse mouth. Drink plenty of water. If symptoms persist, call a physician. Do NOT induce vomiting.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

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

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

Fire may produce irritating, corrosive and/or toxic gases.

Explosion data

Sensitivity to Mechanical Impact

Not impact sensitive.

Sensitivity to Static Discharge

Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

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 Use personal protection recommended in Section 8. Do not touch damaged containers or

spilled material unless wearing appropriate protective clothing.

Environmental precautions Prevent entry into waterways, sewers, basements or confined areas. Do not flush into surface water or sanitary sewer system. See Section 12 for additional ecological information.

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Advice on safe handling Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.

Storage Conditions Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children.

Incompatible materials None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL (ug/m ³)
SODIUM HYDROX 1.0N SOLN 1310-73-2	Ceiling: 2 mg/m ³	TWA: 2 mg/m ³ (vacated) Ceiling: 2 mg/m ³	IDLH: 10 mg/m ³ Ceiling: 2 mg/m ³	N/A

NIOSH IDLH Immediately Dangerous to Life or Health

Other Information Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

Appropriate engineering controls

Engineering Controls The following requirements list high level controls designed to control exposure below the OEL. More specific requirements may apply.

Individual protection measures, such as personal protective equipment

PPE The following high level PPE requirements assume Engineering Controls that reduce exposure below the limit are not in place. More specific requirements may apply

Eye/face protection Tight sealing safety goggles.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Liquid	Appearance	gel
Color	No information available	Odor	No information available
Odor threshold	No information available		

Property

pH	No information available
Melting point/freezing point	176 C
Boiling point / boiling range	No information available

Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limit in Air	
Upper flammability limit:	No information available
Lower flammability limit:	No information available
Vapor pressure	No information available
Vapor density	No information available
Specific Gravity	No information available
Water solubility	43.6 mg/l
Solubility in other solvents	No information available
Partition coefficient	3.5
Autoignition temperature	No information available
Decomposition temperature	No information available
Explosive properties	No information available
Oxidizing properties	No information available

Other Information

Molecular weight	392.57
VOC Content (%)	No information available
Density	No information available
Bulk density	No information available

10. STABILITY AND REACTIVITY

Reactivity

Not defined As Reactive substance

Chemical stability

Stable under normal conditions.

Possibility of Hazardous Reactions

None under normal processing.

Conditions to avoid

Aerosol formation.

Incompatible materials

None known based on information supplied.

Hazardous Decomposition Products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure**Acute toxicity**

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
PURIFIED WATER USP	> 90 mL/kg (Rat)	N/A	N/A
Deoxycholic Acid	= 1 g/kg (Rat)	N/A	N/A
Benzyl Alcohol	= 1230 mg/kg (Rat)	= 2 g/kg (Rabbit)	= 8.8 mg/L (Rat) 4 h
SODIUM CHLORIDE USP	= 3000 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 42 g/m ³ (Rat) 1 h
SODIUM HYDROX 1.0N SOLN	N/A	= 1350 mg/kg (Rabbit)	N/A

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Deoxycholic Acid	Not mutagenic in the standard battery of tests.	No information available.	No information available.	No information available

IATA	Not regulated
IMDG	Not regulated
ADR	Not regulated
ADN	Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA	Listed
DSL/NDSL	Listed
EINECS/ELINCS	Listed

Legend:

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

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

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

US Federal Regulations

SARA 313

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

SARA 311/312 Hazard Categories

Acute health hazard	Yes
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
SODIUM HYDROX 1.0N SOLN 1310-73-2	1000 lb	-	-	X

CERCLA

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

Chemical Name	Hazardous Substances RQs	CERCLA/SARA RQ	Reportable Quantity (RQ)
SODIUM HYDROX 1.0N SOLN 1310-73-2	1000 lb	-	RQ 1000 lb final RQ RQ 454 kg final RQ

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Benzyl Alcohol 100-51-6	-	X	X
SODIUM HYDROX 1.0N SOLN 1310-73-2	X	X	X
Dibasic Sodium Phosphate Anhydrous, USP	X	X	X

7558-79-4			
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16. OTHER INFORMATION

Revision Date 02-Oct-2018
Revision Note No information available

Disclaimer

The information provided in this Material Safety Data Sheet 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 guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered 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 materials or in any process, unless specified in the text.

End of Safety Data Sheet