



# SAFETY DATA SHEET

Revision Date 02-Nov-2016

Version 1.04

## 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  
400 Interpace Parkway, Morris Corporate Center III  
Parsippany, NJ 07054, USA  
+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

<b>General advice</b>	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.
<b>Eye contact</b>	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.
<b>Skin Contact</b>	Consult a physician if necessary. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
<b>Inhalation</b>	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.
<b>Ingestion</b>	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
SODIUM HYDROX 1.0N SOLN 1310-73-2	Ceiling: 2 mg/m <sup>3</sup>	TWA: 2 mg/m <sup>3</sup> (vacated) Ceiling: 2 mg/m <sup>3</sup>	IDLH: 10 mg/m <sup>3</sup> Ceiling: 2 mg/m <sup>3</sup>	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**

<b>Physical state</b>	Liquid	<b>Appearance</b>	gel
<b>Color</b>	No information available	<b>Odor</b>	No information available
<b>Odor threshold</b>	No information available		

<u>Property</u>	<u>Values</u>
<b>pH</b>	No information available
<b>Melting point/freezing point</b>	176 C
<b>Boiling point / boiling range</b>	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 <sup>3</sup> ( 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

**Target Organ Effects** Gastrointestinal tract (GI), Pancreas.

**Numerical measures of toxicity - Product Information**

The following values are calculated based on chapter 3.1 of the GHS document .

ATEmix (oral) 1000

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

Chemical Name	Algae/aquatic plants	Fish	Crustacea
Benzyl Alcohol 100-51-6	35: 3 h Anabaena variabilis mg/L EC50	460: 96 h Pimephales promelas mg/L LC50 static 10: 96 h Lepomis macrochirus mg/L LC50 static	23: 48 h water flea mg/L EC50
SODIUM CHLORIDE USP 7647-14-5	N/A	5560 - 6080: 96 h Lepomis macrochirus mg/L LC50 flow-through 12946: 96 h Lepomis macrochirus mg/L LC50 static 6020 - 7070: 96 h Pimephales promelas mg/L LC50 static 6420 - 6700: 96 h Pimephales promelas mg/L LC50 static 4747 - 7824: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 7050: 96 h Pimephales promelas mg/L LC50 semi-static	1000: 48 h Daphnia magna mg/L EC50 340.7 - 469.2: 48 h Daphnia magna mg/L EC50 Static
SODIUM HYDROX 1.0N SOLN 1310-73-2	N/A	45.4: 96 h Oncorhynchus mykiss mg/L LC50 static	N/A

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient
Benzyl Alcohol 100-51-6	N/A	N/A	N/A	1.1

**Other adverse effects** No information available

**13. DISPOSAL CONSIDERATIONS**

**Waste treatment methods**

**Disposal of wastes** Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated packaging** Do not reuse container. Dispose of contents/containers in accordance with local regulations.

This product contains one or more substances that are listed with the State of California as a hazardous waste.

Chemical Name	California Hazardous Waste Status
SODIUM HYDROX 1.0N SOLN 1310-73-2	Toxic Corrosive

**14. TRANSPORT INFORMATION**

**DOT** Not regulated

**TDG** Not regulated

**ICAO (air)** Not regulated

<b>IATA</b>	Not regulated
<b>IMDG</b>	Not regulated
<b>ADR</b>	Not regulated
<b>ADN</b>	Not regulated

## 15. REGULATORY INFORMATION

### International Inventories

<b>TSCA</b>	Listed
<b>DSL/NDSL</b>	Listed
<b>EINECS/ELINCS</b>	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**

<b>Acute health hazard</b>	Yes
<b>Chronic Health Hazard</b>	No
<b>Fire hazard</b>	No
<b>Sudden release of pressure hazard</b>	No
<b>Reactive Hazard</b>	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

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**16. OTHER INFORMATION**

**Revision Date** 02-Nov-2016  
**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**