



SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	Trulicity™
Registration number	-
Synonyms	None.
LY Number	LY2189265
LSN Number	2189265
Item Code	CT9561, 521556, 521552, 521551, 520150, 519504, 515657, PS140X, ZD1434, PS1431, PS1432, PS1433, PS1434, PS1402, PS1401

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	Pharmaceutical
Uses advised against	None known.

1.3. Details of the supplier of the safety data sheet

Supplier

Company name	Eli Lilly and Company
Address	Lilly Corporate Center Indianapolis, IN 46285 United States

Division

Telephone	Phone:	+1-317-276-2000
e-mail	lilly_msds@lilly.com	

1.4. Emergency telephone number	CHEMTREC:	00 +1 + 703-527-3887
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 as amended

This mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Contains:	Dulaglutide
Hazard pictograms	None.
Signal word	None.
Hazard statements	The mixture does not meet the criteria for classification.

Precautionary statements

Prevention	Not available.
Response	Not available.
Storage	Not available.
Disposal	Not available.

Supplemental label information	None.
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2.3. Other hazards	None known.
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SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Dulaglutide	0,15 - 0,29	-	-	-	
Classification:	-				

Composition comments Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

SECTION 4: First aid measures

General information Not available.

4.1. Description of first aid measures

Inhalation Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately.

Skin contact Wash off immediately with plenty of water for at least 15 minutes. Immediately take off all contaminated clothing. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.

Eye contact Immediately flush eye(s) with plenty of water. Get medical attention.

Ingestion Consult a physician.

4.2. Most important symptoms and effects, both acute and delayed None known.

4.3. Indication of any immediate medical attention and special treatment needed Not available.

SECTION 5: Firefighting measures

General fire hazards This product is an aqueous mixture which will not burn.

5.1. Extinguishing media

Suitable extinguishing media Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media Not available.

5.2. Special hazards arising from the substance or mixture Fire or excessive heat may produce hazardous decomposition products.

5.3. Advice for firefighters

Special protective equipment for firefighters Wear suitable protective equipment.

Special fire fighting procedures Not available.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Wear suitable protective clothing, gloves and eye/face protection.

For emergency responders Not available.

6.2. Environmental precautions Avoid release to the environment.

6.3. Methods and material for containment and cleaning up Use absorbent/adsorbent material to solidify liquids. Clean up promptly by sweeping or vacuum.

6.4. Reference to other sections See Section 8 for personal protective equipment. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. See Section 8 for personal protective equipment.

7.2. Conditions for safe storage, including any incompatibilities Keep refrigerated. Store at: 2 - 8 C. Do not allow material to freeze. Protect from light.

7.3. Specific end use(s) Not available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

Lilly (LEG)

Components

Type

Value

Dulaglutide

TWA (12hrs)

30 ug/m³

TWA (8hrs)

40 ug/m³

Biological limit values

No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures

Excursion Limit is 3 times full shift TWA for no more than 30 minutes not to exceed full shift guideline.

Derived no effect levels (DNELs)

Not available.

Predicted no effect concentrations (PNECs)

Not available.

8.2. Exposure controls

Appropriate engineering controls

Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, local exhaust ventilation, or down-draft booth.

Individual protection measures, such as personal protective equipment

General information

Not available.

Eye/face protection

Safety glasses with side-shields conforming to EN 166.

Skin protection

- Hand protection

Chemical resistant gloves. Protective gloves complying with EN 374.

- Other

Chemical-resistant gloves and impermeable body covering to minimize skin contact.

Respiratory protection

Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Thermal hazards

Not available.

Hygiene measures

Handle in accordance with good industrial hygiene and safety practices.

Environmental exposure controls

Not available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Aqueous solution.

Physical state

Liquid.

Form

Liquid.

Colour

Colorless

Odour

Odourless.

Odour threshold

Not available.

pH

Not applicable.

Melting point/freezing point

Not available.

Initial boiling point and boiling range

Not available.

Flash point

Not applicable.

Evaporation rate

Not applicable.

Flammability (solid, gas)

Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Vapour pressure

Not applicable.

Vapour density

Not applicable.

Relative density

Not available.

Solubility(ies)

Not available.

Partition coefficient (n-octanol/water)

Not available.

Material name: Trulicity™

Version #: 03 Revision date: 17-May-2016 Issue date: 20-November-2014 Supersedes date: 15-December-2015

SDS EU

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Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not applicable.
Explosive properties	Not explosive
Oxidising properties	No oxidizing properties.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	Not water reactive.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	Hazardous polymerisation does not occur.
10.4. Conditions to avoid	None under normal conditions.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	Fire or excessive heat may produce hazardous decomposition products.

SECTION 11: Toxicological information

General information	Not available.
11.1. Information on toxicological effects	
Acute toxicity	Not expected to be active orally.
Skin corrosion/irritation	Due to lack of data the classification is not possible.
Serious eye damage/eye irritation	Due to lack of data the classification is not possible.
Respiratory sensitisation	Due to lack of data the classification is not possible.
Skin sensitisation	Due to lack of data the classification is not possible.
Germ cell mutagenicity	Mutagenicity testing has not been conducted. Due to lack of data the classification is not possible.
Carcinogenicity	Not listed by IARC, NTP, ACGIH or OSHA. In a 2-year carcinogenicity study in rats, dulaglutide caused statistically significant dose-related increases in the incidence of thyroid C-cell tumors (adenomas and carcinomas combined) following once weekly subcutaneous administration of 1.5 mg. The human relevance of these findings is currently unknown. Thyroid C-cell changes were not reported in monkeys or in a 6-month carcinogenicity study in transgenic mice. Based on available data, the classification criteria are not met.
Reproductive toxicity	At high doses, reduced fetal growth and/or skeletal defects were reported in association with maternal effects (decreased food intake/weight gain). Animal studies did not indicate direct harmful effects with respect to fertility. (Subcutaneous) Based on available data, the classification criteria are not met.
Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure	No significant target organ toxicity reported. (Subcutaneous) Based on available data, the classification criteria are not met.
Aspiration hazard	No aspiration toxicity classification
Mixture versus substance information	Not available.
Other information	Not available.

SECTION 12: Ecological information

12.1. Toxicity	Not expected to be harmful to aquatic organisms.
12.2. Persistence and degradability	Not available.
12.3. Bioaccumulative potential	Not available.
Partition coefficient n-octanol/water (log Kow)	Not available.
Bioconcentration factor (BCF)	Not available.
12.4. Mobility in soil	Not available.

12.5. Results of PBT and vPvB assessment Not a PBT or vPvB substance or mixture.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste Not available.

Contaminated packaging Not available.

EU waste code Not available.

Disposal methods/information Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

RID

Not regulated as dangerous goods.

ADN

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code Not available.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, as amended

Not listed.

National regulations Not available.

15.2. Chemical safety assessment Not applicable.

SECTION 16: Other information

List of abbreviations

LEG: Lilly Exposure Guideline

TWA: Time Weighted Average

References

Not available.

Information on evaluation method leading to the classification of mixture

Not applicable.

Lilly Lab Code

Health: 0

Fire: 0

Reactivity: 0

Revision information

Product and Company Identification: Product Codes

Disclaimer

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For additional information contact:

Eli Lilly and Company

Hazard Communication

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