SAFETY DATA SHEET

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

1.1. Product identifier

Product Name: Skyrizi (Risankizumab-rzaa) 150 mg/mL Solution

Synonyms: Skyrizi, BI 655066, ABBV-066, Risankizumab; 150 mg/mL BDS (solution); 150 mg pre-filled syringe (PFS); 150 mg/mL PEN

Drug Code Number: 0074-1050-01; 0074-2100-01

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

Recommended use: Pharmaceuticals
Scientific research and development

1.3. Details of the supplier of the safety data sheet

Supplier: AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
+1-847-932-7900

E-mail Address: AbbVie.SDS@abbvie.com

1.4. Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008
Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

2.2. Label elements

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

2.3. Other hazards

Not determined

SECTION 3: Composition/information on ingredients

Chemical Name	Weight-%	EINECS/ELINCS Number	EU - GHS Substance Classification	REACH Reg. No

Water 7732-18-5	75-90	Present	Not Hazardous*	No data available
Risankizumab-rzaa (ABBV-066; BI 655066) 1612838-76-2	4-20	NA	Not Hazardous*	No data available
Trehalose 6138-23-4	<10	NA	Not Hazardous*	No data available
Sodium Acetate 127-09-3	<1	Present	Not Hazardous*	No data available
Polysorbate 20 9005-64-5	<0.1	NA	Not Hazardous*	No data available
Acetic Acid 64-19-7	<0.01	Present	Skin Corr. 1A (H314) Flam. Liq. 3 (H226)	No data available

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

For the full text of the R-phrases mentioned in this Section, see Section 16
For the full text of the H-Statements mentioned in this Section, see Section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms None known from occupational exposure. Clinical data suggests the following: gastrointestinal upset, abdominal pain, bone and joint pain, anemia, headaches.

Medical Conditions Aggravated by Exposure None known from occupational exposure.

4.3. Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2. Special hazards arising from the substance or mixture

Special Exposure Hazards: Not determined

5.3. Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8.

6.2. Environmental precautions

Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Recover product and place in an appropriate container for disposal.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions.

7.3. Specific end use(s)

Recommended use: Pharmaceuticals
Scientific research and development

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	AbbVie Employee Exposure Limit (OEL):	AbbVie PBLEC Category (OEB):	Skin Notation
Water 7732-18-5	Not applicable	Not determined	None
Risankizumab-rzaa (ABBV-066; BI	120 mcg/m^3	Refer to Employee Exposure Limit	None

655066) 1612838-76-2			
Trehalose 6138-23-4	Not applicable	Not determined	None
Sodium Acetate 127-09-3	Not applicable	Not determined	None
Polysorbate 20 9005-64-5	Not applicable	Not determined	None
Acetic Acid 64-19-7	Not applicable	Not determined	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Acetic Acid 64-19-7	15 ppm STEL	STEL: 10 ppm STEL: 25 mg/m³	10 ppm TWA 25 mg/m³ TWA 20 ppm Peak 50 mg/m³ Peak	15 ppm (STEL) 37 mg/m³ (STEL) 10 ppm (TWA) 25 mg/m³ (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Acetic Acid 64-19-7	25 mg/m³ (TWA)	15 ppm (STEL) 37 mg/m³ (STEL) 10 ppm (TWA) 25 mg/m³ (TWA)	10 ppm (TWA) 25 mg/m³ (TWA) 20 ppm (STEL) 50 mg/m³ (STEL)	

8.2. Exposure controls

Engineering Controls: No special provisions are required under normal product use conditions.

Respiratory Protection: An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Wear eye protection appropriate to exposures when handling the product formulation.

Gloves: Impervious gloves.

Other PPE Data: Wear appropriate body coverings if contact may occur.

Environmental Exposure Controls: Not determined

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: Liquid
Odor: Not determined
Odor Threshold: Not determined
pH: Not determined
Boiling Pt. @ 760 mm Hg (°C): Not determined
Melting/Freezing Point (°C): Not determined
Flash Point (°C): Not determined
Evaporation Rate at 20°C: Not determined
Flammability (Solid): Not determined
Lower Explosive Limit: Not determined
Upper Explosive Limit: Not determined
Vapor Pressure (mm Hg): Not determined
Vapor Density (Air = 1): Not determined
Specific Gravity: Not determined

Solubility(ies): Not determined
Partition coefficient: n-octanol/water Not determined
Autoignition Temp. (°C): Not determined
Decomposition temperature (°C): Not determined
Viscosity (centipoise): Not determined
Explosion Severity: Not determined
Oxidizer Properties: Not determined

9.2. Other information

SECTION 10: Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined

10.4. Conditions to avoid

Not determined

10.5. Incompatible materials

Not determined

10.6. Hazardous decomposition products

Not determined

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Unlikely
Dermal: Unlikely
Inhalation: Unlikely

Acute Toxicity - Oral: Data for component (s) given below:

Chemical Name	Acute Test	Value	Units	Species
Water 7732-18-5	LD50 =	90,000	mg/kg	Rats
Sodium Acetate 127-09-3	LD50 >	3500	mg/kg	Rats Mice
Polysorbate 20 9005-64-5	LD50 =	37,000	mg/kg	Rats

Acetic Acid 64-19-7	LD50 =	3310	mg/kg	Rats

Acute Toxicity - Dermal: Data for component (s) given below:

Chemical Name	Acute Test	Value	Units	Species
Sodium Acetate 127-09-3	LD50 >	10,000	mg/kg	Rabbits
Acetic Acid 64-19-7	LD50 =	1112	mg/kg	Rabbits

Acute Toxicity - Inhalation: Data for component (s) given below:

Chemical Name	Test	Value	Units	Species
Sodium Acetate 127-09-3	LC 50 >	30	mg/L	Rats
Acetic Acid 64-19-7	LC 50 =	5620	ppm	Mice

Other Toxicology Data: Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Risankizumab-rzaa (ABBV-066; BI 655066) 1612838-76-2	NOAEL (sc) = NOAEL (iv) =	50	mg/kg	Monkeys	6 months 4 weeks
Polysorbate 20 9005-64-5	LD50 (iv) =	1420	mg/kg	Mice	None

Corrosivity: Not determined

Dermal Irritation: Active Ingredient(s): Not considered a skin irritant.

Eye irritation: Not determined

Sensitization: Not determined

Toxicokinetics/Metabolism: Not determined

Target Organ Effects Not determined

Reproductive Effects No adverse effects on reproductive tissues in repeat dose toxicology studies.

Carcinogenicity Not determined

Mutagenicity: Data for component (s) given below:

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Sodium Acetate 127-09-3	No Data.	No data available	No Data.	Negative
Acetic Acid 64-19-7	No Data.	Negative	No Data.	No Data.

Aspiration hazard: Not determined

Notes:
1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

SECTION 12: Ecological information

12.1. Toxicity

Data for component (s) given below:

Chemical Name	Weight-%	LC 50 (mg/l)	Species	Duration
Acetic Acid 64-19-7	<0.01	75	Bluegill	96 Hours

Chemical Name	Weight-%	EC50 (daphnia - mg/l)	Species	Duration
Sodium Acetate 127-09-3	<1	1000		
Acetic Acid 64-19-7	<0.01	65	Daphnia magna	24 hours

12.2. Persistence and degradability

Not determined

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined

12.5. Results of PBT and vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. **EC50: Concentration in water that produces 50% mortality in Daphnia sp.**
2. **LC50: Concentration in water that produces 50% mortality in fish.**
3. **EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.**

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

SECTION 14: Transport information

ADR, DOT, ICAO/IATA, IMDG/IMO

Status: Not regulated

14.1. UN number Not applicable
14.2. Proper shipping name: Not applicable
14.3. Hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazard: Not applicable

14.6. Special provisions: Not applicable
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. Safety, health and environmental regulations/legislation specific for the substance or mixture

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Water 7732-18-5	Present	X	X	Not listed	X
Risankizumab-rzaa (ABBV-066; BI 655066) 1612838-76-2	-	-	-	Not listed	-
Trehalose 6138-23-4	-	-	-	Not listed	X
Sodium Acetate 127-09-3	Present	X	X	Not listed	X
Polysorbate 20 9005-64-5	-	X	X	Not listed	X
Acetic Acid 64-19-7	Present	X	X	Not listed	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Water 7732-18-5	-	-	X	X	Present	
Risankizumab-rzaa (ABBV-066; BI 655066) 1612838-76-2	-	-	-	-	-	
Trehalose 6138-23-4	-	Present	X	X	-	
Sodium Acetate 127-09-3	Present	Present	X	X	Present	HSR003156
Polysorbate 20 9005-64-5	-	-	X	X	Present	
Acetic Acid 64-19-7	Present	Present	X	X	Present	HSR000975,HSR001580,HSR001581,HSR001582

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
ISHL - Japan Industrial Safety and Health Law
IECSC - China Inventory of Existing Chemical Substances
AICS - Australian Inventory of Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Weight-%	NTP:	IARC:	ACGIH:
Water	75-90	Not listed	Not listed	Not listed
Risankizumab-rzaa (ABBV-066; BI 655066)	4-20	Not listed	Not listed	Not listed
Trehalose	<10	Not listed	Not listed	Not listed
Sodium Acetate	<1	Not listed	Not listed	Not listed

Polysorbate 20	<0.1	Not listed	Not listed	Not listed
Acetic Acid	<0.01	Not listed	Not listed	Not listed

SARA 313 Information

Chemical Name	Weight-%	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Water	75-90	No	Not applicable	Not applicable
Risankizumab-rzaa (ABBV-066; BI 655066)	4-20	No	Not applicable	Not applicable
Trehalose	<10	No	Not applicable	Not applicable
Sodium Acetate	<1	No	Not applicable	Not applicable
Polysorbate 20	<0.1	No	Not applicable	Not applicable
Acetic Acid	<0.01	No	5000 lb 2270 kg	Not applicable

RCRA Status: Not determined

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

WHMIS Hazard Class Not determined

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

SECTION 16: Other information

Document Authored By: Occupational and Environmental Toxicology

Issued: Mar-10-2021

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