



SAFETY DATA SHEET

Revision date 14-Jun-2025

Version 4

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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

| | |
|------------------|------------------------------|
| Product Name | Ibutilide Fumarate Injection |
| Product Code(s) | IBUTILIDE FUMARATE INJECTION |
| Trade Name: | Corvert Injection |
| Item Code | H00016876 |
| Chemical Family: | Mixture |

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

| | |
|-----------------|--|
| Recommended Use | Pharmaceutical product used as cardiovascular drug |
|-----------------|--|

1.3. Details of the supplier of the safety data sheet

Pfizer Inc
66 Hudson Boulevard East
New York, New York 10001
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

| | |
|----------------|------------------------|
| E-mail address | pfizer-MSDS@pfizer.com |
|----------------|------------------------|

1.4. Emergency telephone number

| | |
|---------------------|---|
| Emergency Telephone | Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887 |
|---------------------|---|

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Not classified as hazardous.

OSHA Classification

Hazards not otherwise classified (HNOC)

Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

Not applicable

2.2. Label elements

| | |
|-------------------|---|
| Signal word | Not classified |
| Hazard statements | Not classified in accordance with international standards for workplace safety. |

2.3. Other hazards

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Other hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

PBT & vPvB The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances Not applicable

3.2 Mixtures

Hazardous

| Chemical name | Weight-% | REACH registration number | EC No (EU Index No) | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Specific concentration limit (SCL) | M-Factor | M-Factor (long-term) |
|---|----------|---------------------------|---------------------|---|------------------------------------|-------------------|----------------------|
| Ibutilide Fumarate (CAS #: 122647-32-9) | 0.01 | | Not Listed | Repr. 1B,H360D; Eye Irrit. 2A,H319 | Not classified | No data available | No data available |

NonHazardous

| Chemical name | Weight-% | REACH registration number | EC No (EU Index No) | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Specific concentration limit (SCL) | M-Factor | M-Factor (long-term) |
|--|----------|---------------------------|---------------------|---|------------------------------------|-------------------|----------------------|
| Water (CAS #: 7732-18-5) | * | - | 231-791-2 | Not classified | Not classified | No data available | No data available |
| SODIUM CHLORIDE (CAS #: 7647-14-5) | * | - | 231-598-3 | Not classified | Not classified | No data available | No data available |
| Sodium acetate trihydrate (CAS #: 6131-90-4) | * | | Not Listed | Not classified | Not classified | No data available | No data available |

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate No information available

| Chemical name | Oral LD50 mg/kg | Dermal LD50 mg/kg | Inhalation LC50 - 4 hour - dust/mist - mg/L | Inhalation LC50 - 4 hour - vapor - mg/L | Inhalation LC50 - 4 hour - gas - ppm |
|--------------------------------|-----------------|-------------------|---|---|--------------------------------------|
| Ibutilide Fumarate 122647-32-9 | >500 | No data available | No data available | No data available | No data available |
| Water 7732-18-5 | 89838.9 | No data available | No data available | No data available | No data available |

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| Chemical name | Oral LD50 mg/kg | Dermal LD50 mg/kg | Inhalation LC50 - 4 hour - dust/mist - mg/L | Inhalation LC50 - 4 hour - vapor - mg/L | Inhalation LC50 - 4 hour - gas - ppm |
|------------------------------|-----------------|-------------------|---|---|--------------------------------------|
| SODIUM CHLORIDE 7647-14-5 | 3550 | 10000 | No data available | No data available | No data available |

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59).

Additional information

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret. Non-hazardous ingredients provided for completeness.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

| | |
|---------------------|--|
| Inhalation | Remove to fresh air. Seek immediate medical attention/advice. |
| Eye contact | Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician. |
| Skin contact | Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention. |
| Ingestion | Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately. |

4.2. Most important symptoms and effects, both acute and delayed

| | |
|--|--|
| Most important symptoms and effects | For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information. |
|--|--|

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

| | |
|---------------------------|-------|
| Note to physicians | None. |
|---------------------------|-------|

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

| | |
|-------------------------------------|--|
| Suitable Extinguishing Media | Use extinguishing agent suitable for type of surrounding fire. |
|-------------------------------------|--|

5.2. Special hazards arising from the substance or mixture

| | |
|---|--|
| Specific hazards arising from the chemical | Fine particles (such as dust and mists) may fuel fires/explosions. |
| Hazardous combustion products | Formation of toxic gases is possible during heating or fire. |
| Explosion data | |
| Sensitivity to mechanical impact | No information available. |
| Sensitivity to static discharge | No information available. |

5.3. Advice for firefighters

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Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.
Methods for cleaning up Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

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Pfizer OEL TWA-8 Hr: 5 µg/m³

SODIUM CHLORIDE

Latvia
Russia

TWA: 5 mg/m³;
MAC: 5 mg/m³

Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal protective equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Eye/face protection

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).

Thermal hazards

No information available.

Environmental exposure controls

No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state

Liquid

Color

Colorless

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Odor No information available.
Odor threshold No information available

| <u>Property</u> | <u>Values</u> |
|---|--------------------------|
| Melting point / freezing point | No data available |
| Boiling point or initial boiling point and boiling range | No data available |
| Flammability (solid, gas) | No data available |
| Lower and upper explosion limit/flammability limit | |
| Lower explosion limit | No data available |
| Upper explosion limit | No data available |
| Flash point | No data available |
| Autoignition temperature | No data available |
| Decomposition temperature | |
| SADT (°C) | No data available |
| pH | No data available |
| pH (as aqueous solution) | No data available |
| Kinematic viscosity | No data available |
| Dynamic viscosity | No data available |
| Solubility | Soluble Water |
| Vapor pressure | No data available |
| Density and/or relative density | No data available |
| Bulk density | No data available |
| Liquid Density | No data available |
| Vapor density | No data available |
| Particle characteristics | |
| Particle Size | No information available |
| Particle Size Distribution | No information available |

9.2. Other information

Molecular formula Mixture
Molecular weight Mixture

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

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10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

| | |
|--|---|
| General Information: | The information included in this section describes the potential hazards of the individual ingredients |
| Long Term: | Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system the developing fetus. |
| Known Clinical Effects: | Convulsions possible at high overdosage. Clinical use of this drug has caused headache, nausea, vomiting, changes in heart rate, impaired heart conduction (atrioventricular block), changes in blood pressure. |
| Acute toxicity | Based on available data, the classification criteria are not met. |
| Serious eye damage/eye irritation | Based on available data, the classification criteria are not met. |
| Skin corrosion/irritation | Based on available data, the classification criteria are not met. |
| Respiratory or skin sensitization | Based on available data, the classification criteria are not met. |
| STOT - single exposure | Based on available data, the classification criteria are not met. |
| STOT - repeated exposure | Based on available data, the classification criteria are not met. |
| Reproductive toxicity | Based on available data, the classification criteria are not met. |
| Germ cell mutagenicity | Based on available data, the classification criteria are not met. |
| Carcinogenicity | Based on available data, the classification criteria are not met. |
| Aspiration hazard | Based on available data, the classification criteria are not met. |

Acute Toxicity: (Species, Route, End Point, Dose)

SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³
Rat Oral LD 50 3 g/kg
Mouse Oral LD 50 4 g/kg
Rabbit Dermal LD 50 > 10 g/kg

Ibutilide Fumarate

Rat Oral LD 50 > 500 mg/kg
Rat Para-periosteal LD 50 50 mg/kg

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|-----------------|----------------------|--------------------------|-----------------------|
| Water | > 90 mL/kg (Rat) | - | - |
| SODIUM CHLORIDE | = 3550 mg/kg (Rat) | > 10000 mg/kg (Rabbit) | > 42 mg/L (Rat) 1 h |

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

SODIUM CHLORIDE

Skin irritation Rabbit Mild
Eye irritation Rabbit Mild

Ibutilide Fumarate

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Non-irritating

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Ibutilide Fumarate

14 Day(s) Rat Intravenous 12.5 mg/kg LOAEL Central nervous system
14 Day(s) Dog Intravenous < 2.5 mg/kg/day NOAEL

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90 Day(s) Rat Oral 4 mg/kg/day NOAEL Liver, Gastrointestinal system
90 Day(s) Dog Oral 4 mg/kg/day NOEL Central Nervous System, Male reproductive system

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Ibutilide Fumarate

Reproductive & Fertility Rat Oral 5 mg/kg/day NOAEL Developmental toxicity
Reproductive & Fertility Rat Oral 5 mg/kg/day NOAEL Maternal Toxicity
Reproductive & Fertility Rat Oral 5 mg/kg/day NOAEL Paternal toxicity
Embryo / Fetal Development Rat Oral 5 mg/kg/day NOAEL Not Teratogenic
Embryo / Fetal Development Rabbit Oral 20 mg/kg/day LOAEL Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Ibutilide Fumarate

Bacterial Mutagenicity (Ames) *Salmonella* Negative
Unscheduled DNA Synthesis Negative
In Vitro Micronucleus Negative
Mammalian Cell Mutagenicity Mouse Lymphoma Negative

Carcinogenicity None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Based on available data, the classification criteria are not met. Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

12.1. Toxicity

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment Based on available data, the classification criteria are not met.

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| | |
|-----------------|--|
| Chemical name | PBT and vPvB assessment |
| SODIUM CHLORIDE | Not PBT/vPvB PBT assessment does not apply |

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.

PMT or vPvM properties Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

| | |
|------------------------------------|----------------|
| UN number: | Not applicable |
| UN proper shipping name: | Not applicable |
| Transport hazard class(es): | Not applicable |
| Packing group: | Not applicable |
| Environmental Hazard(s): | Not applicable |

Section 15: REGULATORY INFORMATION

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

| | |
|---|------------|
| Ibutilide Fumarate | |
| CERCLA/SARA Section 313 de minimus % | Not Listed |
| California Proposition 65 | Not Listed |
| EINECS | Not Listed |
| Water | |
| CERCLA/SARA Section 313 de minimus % | Not Listed |
| California Proposition 65 | Not Listed |
| TSCA | Present |

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| | |
|---|------------|
| EINECS | 231-791-2 |
| AICS | Present |
| SODIUM CHLORIDE | |
| CERCLA/SARA Section 313 de minimus % | Not Listed |
| California Proposition 65 | Not Listed |
| TSCA | Present |
| EINECS | 231-598-3 |
| AICS | Present |
| Sodium acetate trihydrate | |
| CERCLA/SARA Section 313 de minimus % | Not Listed |
| California Proposition 65 | Not Listed |
| EINECS | Not Listed |
| AICS | Present |

National regulations

| Chemical name | French RG number |
|------------------------------|------------------|
| SODIUM CHLORIDE 7647-14-5 | RG 78 |

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905

Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable

Storage of Hazardous Material Not applicable

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable

Major Accidents Ordinance SR 814.012 Not applicable

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

| Chemical name | EU - Plant Protection Products (1107/2009/EC) |
|------------------------------|---|
| SODIUM CHLORIDE 7647-14-5 | Plant protection agent |

| Chemical name | Biocidal Products Regulation (EU) No 528/2012 (BPR) |
|------------------------------|---|
| SODIUM CHLORIDE 7647-14-5 | Product-type 1: Human hygiene |

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Explosives Precursors Marketing and Use (2019/1148)

Not applicable

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
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing Chemicals Inventory
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals
TCSI - Taiwan Chemical Substance Inventory

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of any hazard and/or precautionary statements referred to under Sections 2-15

H360D - May damage the unborn child H319 - Causes serious eye irritation

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients. Publicly available toxicity information.

Reason for revision Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 5 - Fire Fighting Measures. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

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Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.