

Revision Date: 11/06/2023

#### 1. Identification

1.1. Product identifier

**Product Identity** ChiRhoStim®, Human Secretin for Injection, Acetate

**Alternate Names** ChiRhoStim®, Human Secretin for Injection, Acetate

, H-His-Ser-Asp-Gly-Thr-Phe-Thr-Ser-Glu-Leu-Ser-Arg-Leu-Arg-Glu-Gly-Ala-Arg-Leu-

Gln-Arg-Leu-Leu-Gln-Gly-Leu-Val-NH2, Product Code: FP-0711, P-0711,

NDC Number: 67066-005-01

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

Intended use Medical Use.

1.3. Details of the supplier of the safety data sheet

**Company Name** ChiRhoClin, Inc

4000 Blackburn Lane, Suite 270

Burtonsville, MD 20866

**Emergency** 

301-476-8388 **Customer Service:** 

## 2. Hazard(s) identification

Based on the toxicity studies (see item 11) human secretin offers little potential for acute toxicity in man. However, it is still prudent to minimize and exercise due care in regards to exposure to pure human secretin powder. Human secretin pure powder should not be swallowed or inhaled. No data is available to suggest absorption through the skin.

#### 2.1. Classification of the substance or mixture

No applicable GHS categories.

#### 2.2. Label elements

No applicable GHS categories.

#### [Prevention]

No GHS prevention statements

#### [Response]

No GHS response statements

#### [Storage]

No GHS storage statements

#### [Disposal]

No GHS disposal statements



Revision Date: 11/06/2023

## 3. Composition/information on ingredients

This product contains the following substances that present a hazard within the meaning of the relevant State and Federal Hazardous Substances regulations.

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
Secretin, human CAS Number: 0108153-74-8	100	Not Classified	

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

### Section 4. First aid measures

#### 4.1. Description of first aid measures

General In all cases of doubt, or when symptoms persist, seek medical attention.

Never give anything by mouth to an unconscious person.

Inhalation Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give

artificial respiration. If unconscious, place in the recovery position and obtain immediate

medical attention. Give nothing by mouth.

**Eyes** Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and

seek medical attention.

Skin Remove contaminated clothing. Wash skin thoroughly with soap and water or use a

recognized skin cleanser.

Ingestion If swallowed obtain immediate medical attention. Keep at rest. Do NOT induce vomiting.

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

Overview No specific symptom data available.

Treat symptomatically.

# Section 5. Fire-fighting measures

#### 5.1. Extinguishing media

Carbon dioxide, dry chemical powder or appropriate form.

#### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition: Carbon Monoxide, Carbon Dioxide, Nitrogen Oxides, Sulfur Oxides.

#### 5.3. Advice for fire-fighters

As with all fires, wear positive pressure, self-contained breathing apparatus, (SCBA) with a full face piece and protective clothing. Persons without respiratory protection should leave area. Wear SCBA during clean-up immediately after fire. No smoking.

**ERG Guide No.** 

<sup>\*</sup>PBT/vPvB - PBT-substance or vPvB-substance.

The full texts of the phrases are shown in Section 16.



Revision Date: 11/06/2023

## Section 6. Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

Put on appropriate personal protective equipment (see section 8).

#### 6.2. Environmental precautions

Do not allow spills to enter drains or waterways.

Use good personal hygiene practices. Wash hands before eating, drinking, smoking, or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

#### 6.3. Methods and material for containment and cleaning up

Sweep up or pick up.

# Section 7. Handling and storage

#### 7.1. Precautions for safe handling

Handle containers carefully to prevent damage and spillage.

#### 7.2. Conditions for safe storage, including any incompatibilities

Store below -20°C in a desiccated environment and protected from light. Containers of this material may be hazardous when empty since they retain product residues (dust, solids); observe all warnings and precautions listed for the product.

Incompatible materials: No data available.

#### 7.3. Specific end use(s)

No data available.

# Section 8. Exposure controls / personal protection

#### 8.1. Control parameters

#### **Exposure**

CAS No.	Ingredient	Source	Value
0108153-74-8	Secretin, human	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit

The exposure limits for nuisance dust are: OSHA PEL: 15 mg/m<sup>3</sup> (50 mppcf\*) TWA, ACGIH 10 mg/m<sup>3</sup>.

#### 8.2. Exposure controls

If workers are exposed to concentrations above the exposure limit, they must use the Respiratory

appropriate, certified respirators.

Protective safety glasses recommended **Eyes** 



# Safety Data Sheet ChiRhoStim®, Human Secretin for Injection, Acetate

Revision Date: 11/06/2023

**Skin** Protective gloves recommended.

**Engineering Controls** Provide adequate ventilation. Where reasonably practicable this should be achieved by the

use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and any vapor below occupational exposure limits

suitable respiratory protection must be worn.

**Other Work Practices** Use good personal hygiene practices. Wash hands before eating, drinking, smoking, or

using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

## Section 9. Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Appearance Color: Not provided Physical State: Solid

Odor Not provided
Odor threshold Not determined
pH Not Measured

Melting point / freezing point
Not Measured
Initial boiling point and boiling range
Not Measured
Flash Point
Not Measured
Evaporation rate (Ether = 1)
Not Measured

**Evaporation rate (Ether = 1)**Not Measured **Flammability (solid, gas)**Not Applicable

Upper/lower flammability or explosive limits Lower Explosive Limit: Not Measured

Upper Explosive Limit: Not Measured

Vapor pressure (Pa)Not MeasuredVapor DensityNot MeasuredRelative DensityNot Measured

Solubility in Water

Soluble in 1% Acetic Acid at a concentration of 1 mg/mL
Soluble in water at concentrations greater than 1 mg/mL

Not Measured

Partition coefficient n-octanol/water (Log Kow)

Auto-ignition temperatureNot MeasuredDecomposition temperatureNot MeasuredViscosity (cSt)Not Measured

VOC Content

Particle Characteristics

9.2. Other information

No other relevant information.

Revision Date: 11/06/2023

# Section 10. Stability and reactivity

#### 10.1. Reactivity

Hazardous Polymerization will not occur.

#### 10.2. Chemical stability

Stable under normal circumstances.

#### 10.3. Possibility of hazardous reactions

No data available.

#### 10.4. Conditions to avoid

No data available.

#### 10.5. Incompatible materials

No data available.

#### 10.6. Hazardous decomposition products

Carbon Monoxide, Carbon Dioxide, Nitrogen Oxides, Sulfur Oxides.

# Section 11. Toxicological information

#### **Acute toxicity**

Human Secretin Acute Toxicity Study at doses 100 times the human dose (40 mcg/kg; 2.8 mg/70kg) orally to male and female mice and intravenously to male and female rabbits were nontoxic.

Human Secretin Fourteen (14) Day Intravenous Chronic Toxicity Study in male and female rats at doses of 0.4 and 10 mcg/kg/day had no observable toxic effect. The high dose was equivalent to a total dose of 9.8 mg in a 70 kg human. A Human Secretin Fourteen (14) Day Intravenous Chronic Toxicity Study in male and female beagles at doses of 1.5 and 5 mcg/kg/day had no observable toxic effect. The high dose for beagles was equivalent to a total dose of 4.9 mg in a 70 kg human.

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LC50, mg/L/4hr	Inhalation Dust/Mist LC50, mg/L/4hr	Inhalation Gas LC50, ppm
Secretin, human - (108153-74-8)	No data available.	No data available.	No data available.	No data available.	No data available.

#### **Carcinogen Data**

CAS No.	Ingredient	Source	Value		
0108153-74-8	Secretin, human	OSHA	Regulated Carcinogen: No;		
		NTP	Known: No; Suspected: No;		
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;		
		ACGIH	No Established Limit		



Revision Date: 11/06/2023

Classification	Category	Hazard Description
Acute toxicity (oral)		Not Applicable
Acute toxicity (dermal)		Not Applicable
Acute toxicity (inhalation)		Not Applicable
Skin corrosion/irritation		Not Applicable
Serious eye damage/irritation		Not Applicable
Respiratory sensitization		Not Applicable
Skin sensitization		Not Applicable
Germ cell mutagenicity		Not Applicable
Carcinogenicity		Not Applicable
Reproductive toxicity		Not Applicable
STOT-single exposure		Not Applicable
STOT-repeated exposure		Not Applicable
Aspiration hazard		Not Applicable

# Section 12. Ecological information

#### 12.1. Toxicity

No additional information provided for this product. See Section 3 for chemical specific data.

#### **Aquatic Ecotoxicity**

Ingredient	96 hr LC50 fish,	48 hr EC50 crustacea,	ErC50 algae,	
	mg/L	mg/L	mg/L	
Secretin, human - (108153-74-8)	No data available.	No data available.	No data available.	

#### 12.2. Persistence and degradability

There is no data available on the preparation itself.

#### 12.3. Bioaccumulative potential

Not Measured

#### 12.4. Mobility in soil

No data available.

#### 12.5. Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

#### 12.6. Other adverse effects

No data available.



# Safety Data Sheet ChiRhoStim®, Human Acetate

Revision Date: 11/06/2023

# Section 13. Disposal considerations

#### 13.1. Waste treatment methods

Waste should not be released to sewers. Observe all federal, state, and local regulations when disposing of this substance.

### Section 14. Transport information

**DOT (Domestic Surface** IMO / IMDG (Ocean ICAO/IATA Transportation) Transportation) 14.1. UN number Not Regulated Not Regulated Not Regulated 14.2. UN proper shipping Not Regulated Not Regulated Not Regulated name 14.3. Transport hazard **DOT Hazard Class:** Not **IMDG:** Not Applicable Air Class: Not class(es) Applicable Sub Class: Not Applicable Sub Class: Not Applicable Applicable Sub Class: Not Applicable Not Applicable 14.4. Packing group Not Applicable Not Applicable

14.5. Environmental hazards

Marine Pollutant: No;

14.6. Special precautions for user

Not Applicable

# Section 15. Regulatory information

**Regulatory Overview** The regulatory data in Section 15 is not intended to be all-inclusive, only selected

regulations are represented.

All components of this material are either listed or exempt from listing on the TSCA **Toxic Substance** 

**Control Act (TSCA)** Inventory.

#### **EPCRA 302 Extremely Hazardous:**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

#### **EPCRA 313 Toxic Chemicals:**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

#### Proposition 65 - Carcinogens (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

#### **Proposition 65 - Developmental Toxins (>0.0%):**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

#### **Proposition 65 - Female Repro Toxins (>0.0%):**

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.



# Safety Data Sheet ChiRhoStim®, Human Secretin for Injection, Acetate

Revision Date: 11/06/2023

#### Proposition 65 - Male Repro Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

#### **Proposition 65 Label Warning:**

This product contains no chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

### Section 16. Other information

#### **Revision Date** 11/06/2023

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

Not Applicable

Disclaimer: The information presented herein is supplied as a guide to those who handle or use this product. Safe work practices must be employed when working with any materials. It is important that the end user makes a determination regarding the adequacy of the safety procedures employed during the use of this product.

**End of Document**