



# SAFETY DATA SHEET

## SECTION 1 - IDENTIFICATION

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### Product Identification:

|  |                   |
|--|-------------------|
| Yosprala (aspirin and omeprazole) delayed-release tablets, 325 mg/40 mg, 30 count bottle | NDC 64950-0425-30 |
| Yosprala (aspirin and omeprazole) delayed-release tablets, 325 mg/40 mg, 90 count bottle | NDC 64950-0425-90 |
| Yosprala (aspirin and omeprazole) delayed-release tablets, 81 mg/40 mg, 30 count bottle  | NDC 64950-0424-30 |
| Yosprala (aspirin and omeprazole) delayed-release tablets, 81 mg/40 mg, 90 count bottle  | NDC 64950-0424-90 |

**Recommended use and restrictions:** YOSPRALA is a combination of aspirin, an anti-platelet agent, and omeprazole, a proton pump inhibitor (PPI). Yosprala is a delayed-release tablets indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers.

YOSPRALA contraindicated for patients with history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Also in pediatric patients with suspected viral infections, with or without fever, because of the risk of Reye's Syndrome and patients receiving rilpivirine-containing products.

Do not split, chew, crush or dissolve the tablet.

**Manufacturer Name:** Genus Lifesciences Inc.  
**Manufacturer Address:** 514 N. 12<sup>th</sup> Street  
Allentown, PA 18102

**Fax number:** (610) 782-9781  
**Emergency number:** (610) 782-9780 ext.100

## SECTION 2 – HAZARD (S) IDENTIFICATION

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### Classification of the substance or mixture (GHS):

Pictogram:



Signal Word:

Warning



Hazard Statement: It may cause skin irritation or allergic skin reaction. Causes serious eye irritation, and may cause respiratory irritation. It's harmful to aquatic life with long lasting effects.

### **SECTION 3 – COMPOSITION / INFORMATION OF INGREDIENTS**

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| <b>Chemical Identity</b> | <b>Other Names</b>       | <b>CAS Number</b> |
|--------------------------|--------------------------|-------------------|
| Aspirin                  | Acetylsalicylic acid     | 50-78-2           |
| Omeprazole               | Losec, Prilosec, Zegerid | 73590-58-6        |

### **SECTION 4 – FIRST AID MEASURES**

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Eye Contact: Flush with water while holding eyelids open for at least 20 minutes. Remove contact lenses if worn. Seek medical attention.

Skin Contact: Immediately flush skin with running water for at least 20 minutes. Seek medical attention.

Ingestion: If an accidental ingestion of large amounts occur rinse mouth. Seek medical attention. Do not give anything by mouth to an unconscious person.

Inhalation: Should not pose a hazard. If breathing is difficult, move to fresh air and seek medical attention.

Note to Physicians: All treatments should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.

### **SECTION 5 – FIREFIGHTING MEASURES**

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Extinguishing media: Use carbon dioxide, dry chemical, water spay, foam, sand or any material appropriate for fire in the surrounding area.

Fire / Explosion Hazards: Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. No direct explosion hazard.

Advice to the firefighters: Wear self-contained breathing apparatus for the firefighting and full protective clothing. Prevent fire-fighting water from entering environment.

### **SECTION 6 – ACCIDENTAL RELEASE MEASURES**

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#### **Personal precautions, protective equipment and emergency procedures:**

Exposure Limits: Not Available



Emergency Procedure: As an immediate precautionary measure, isolate the spill or leak area for at least 75 feet in all directions. Keep unauthorized personnel away.

Personal Protection: Personnel should wear appropriate personal protective equipment and minimize exposure. Do not walk through spilled material.

Environmental precautions: Avoid run off to waterways and sewers.

### Methods and Materials for containment and clean up:

Use appropriate personal protective equipment. Contain the source if is safe to do so. Dispose according to applicable regulations.

## SECTION 7 – HANDLING AND STORAGE

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Precaution for safe handling: Use only with adequate ventilation. Wear appropriate personal protective equipment. Use with adequate ventilation.

Conditions for safe storage: Keep container closed. Store in a well-ventilated place. Keep out of reach of children. For more information, follow as directed in product packaging.

## SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

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Exposure limits:

| Ingredient | ACGIH TLV           | NIOSH TWA           | OSHA PEL            |
|------------|---------------------|---------------------|---------------------|
| Aspirin    | 5 mg/m <sup>3</sup> | 5 mg/m <sup>3</sup> | 5 mg/m <sup>3</sup> |
| Omeprazole | NA                  | NA                  | NA                  |

Respiratory protection: Not required when handling solid or containers. If it found to be necessary, wear appropriate NIOSH approved respirator.

Ventilation: Handle material under adequate ventilation.

Protective gloves: Chemical compatible

Eye protection: Safety glasses or goggles

Other personal protection: Do not eat, drink or smoke during use.



## **SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES**

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|                    |         |                   |          |
|--------------------|---------|-------------------|----------|
| Appearance:        | Tablets | Odor:             | Odorless |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture  |
| Physical State:    | Solid   | Solubility:       | N/A      |

## **SECTION 10 – STABILITY AND REACTIVITY**

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|                          |   |
|--------------------------|---|
| Chemical stability:      | Stable under normal conditions of use.                      |
| Reactivity:              | No dangerous reaction known under conditions of normal use. |
| Incompatible materials:  | N/A   |
| Hazardous decomposition: | Will not occur.   |

## **SECTION 11 – TOXICOLOGICAL INFORMATION**

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|                     |  |
|---------------------|--|
| Carcinogenicity:    | Not established for the mixture.   |
| Routes of exposure: | Ingestion; Inhalation; Skin and Eye contact  |
| Acute toxicity:     | May be harmful if swallowed in large quantities  |
| Inhalation effects: | Under normal condition of use; inhalation of fine dust particles is not expected to occur. Dust of the product, if present, may cause respiratory irritation after an excessive inhalation exposure. |
| Skin contact:       | If user operations generate dust or fumes, dust may cause mechanical irritation.   |
| Eye contact:        | If user operations generate dust or fumes, dust may cause mechanical irritation.   |
| Ingestion:          | Ingestion may cause nausea and vomiting.   |

## **SECTION 12 – ECOLOGICAL INFORMATION**

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|                            |  |
|----------------------------|--|
| Toxicity information:      | Harmful to aquatic life with long lasting effects. |
| Persistence:               | Degradability aerobic                              |
| Biodegradation [%]:        | No data available.                                 |
| Environmental precautions: | Avoid release to the environment.                  |



## **SECTION 13 – DISPOSAL INFORMATION**

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Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

## **SECTION 14 – TRANSPORT INFORMATION**

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This product is not regulated for the safe transport of hazardous chemicals under USDOT regulations.

## **SECTION 15 – REGULATORY INFORMATION**

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This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Federal Drug Administration (FDA):                      Approved prescription medication

## **SECTION 16 – OTHER INFORMATION**

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See current package insert for further information.

SDS prepared by Genus Lifesciences Inc.

Issue Date: 03/19/19, New SDS

Revision Date: N/A

This Safety Data Sheet cancels and replaces all preceding SDS for this product.

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