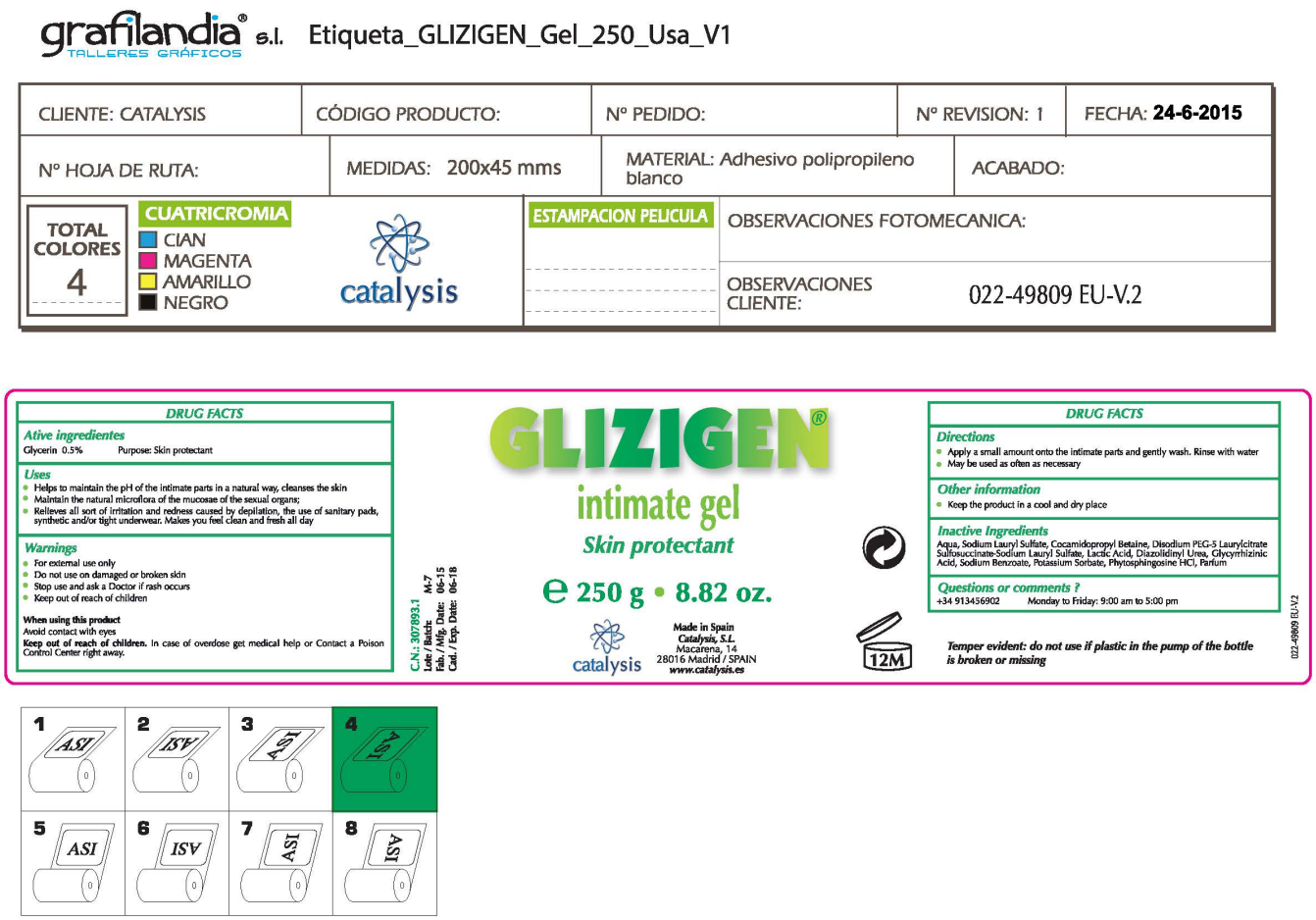
GLIZIGEN GEL INTIMATE- glycerin gel
Catalysis, SL

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Glizigen Intimate Gel

Glycerin 0.5%.....Skin Protectant



- Stop use and ask a doctor if rash occurs
- Children under 6 months: ask a doctor

- Keep out of reach of children

- For external use only.
- Do not use on damaged or broken skin.
- When using this product keep our of the eyes. Rinse with water to remove.
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- Children under 6 months: as a doctor.

- Apply a small amount the intimate parts and gently wash. Rinse with water
- Maybe used as often as necessary

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+ 34 913456902 Monday to Friday: 9:00 am to 5:00 pm

- keep the product in a cool and dry place

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- Maybe used as often as necessary

Water, Sodium Lauryl Sulfate, Cocamidopropyl Betaine, Disodium Laureth Sulfosuccinate, Lactic Acid, Diazolidinyl Urea, Glycyrrhizinic,Acid, Sodium Benzoate, Potassium Sorbate, Phytosphingosine HCl, Parfum

GLIZIGEN GEL INTIMATE

glycerin gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64539-017
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	0.5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	12 mg in 1 mL
GLYCYRRHIZIN (UNII: 6FO62043WK)	0.1 mg in 1 mL
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.1 mg in 1 mL
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	20 mg in 1 mL
DISODIUM LAURETH SULFOSUCCINATE (UNII: D6DH1DTN7E)	3 mg in 1 mL
LACTIC ACID (UNII: 33X04XA5AT)	0.36 mg in 1 mL
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	0.3 mg in 1 mL
SODIUM BENZOATE (UNII: OJ245FE5EU)	0.1 mg in 1 mL
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	0.01 mg in 1 mL
WATER (UNII: 059QF0KO0R)	100 mg in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:64539-017-02	1 in 1 BOTTLE	03/18/2018	
1	NDC:64539-017-01	250 mL in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/18/2018	

Labeler - Catalysis, SL (862795119)

Registrant - Catalysis, SL (862795119)

Establishment

Name	Address	ID/FEI	Business Operations

Catalysis, SL		862795119	manufacture(64539-017)