

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 19.09.2014

Version number 1

Revision: 19.09.2014

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

- **1.1 Product identifier**
- **Trade name:** Lotion 20% IR3535
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the preparation :** Preparation
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Omega Pharma NV
Venecoweg, 26
B-9810 Nazareth
www.omega-pharma.be
T +32 (0)9 381 02 00
Fax : +32 9 381 02 20
Mail : info@omega-pharma.com
- **1.4 Emergency telephone number:**
France (ORFILA 24h/24) - Tel : +33 (0)1 45 42 59 59
Ireland - Tel : 00 353 1 8092568 - 00 353 1 8379964 (24h/24)
EU Tel : 112

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008 :**



Eye Irrit. 2 H319 Causes serious eye irritation.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC :** Not applicable.
- **Information concerning particular hazards for human and environment:**
The product has to be labelled in the latest valid version according to the calculation procedure of the "General Classification guideline for preparations of the EU" .
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



- **Signal word** Warning
- **Hazard statements**
H319 Causes serious eye irritation.
- **Precautionary statements**
P102 Keep out of reach of children.
P264 Wash hands thoroughly after handling.

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P305+P351+P338 **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

- **Labelling of packages where the contents do not exceed 125 ml**
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard statements** Not classified as hazardous for transport
- **Precautionary statements**
P102 Keep out of reach of children.
P264 Wash hands thoroughly after handling.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture: consisting of the following components.

· **Dangerous components:**

CAS: 52304-36-6	ethyl N-acetyl-N-butyl-β-alaninate	 Xi R36	10-25%
EINECS: 257-835-0		 Eye Irrit. 2, H319	

- **Additional information:** For the wording of the listed risk phrases, refer to section 16.

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **After excessive inhalation:** Supply fresh air; consult a doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult a doctor.
- **4.2 Most important symptoms and effects, both acute and delayed :**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed :**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture :** No further relevant information available.

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- 5.3 Advice for firefighters
- Protective equipment: No special measures required.

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures : Not required.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- 6.3 Methods and material for containment and cleaning up:
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- 6.4 Reference to other sections :
See Section 7 for information on safe handling.
See Section 8 for information on personal protective equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- 7.1 Precautions for safe handling : No special precautions are necessary if used correctly.
- Information about fire - and explosion protection: No special measures required.
- 7.2 Conditions for safe storage, including any incompatibilities
- Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- Information about storage in one common storage facility: Not required.
- Further information about storage conditions: None.
- 7.3 Specific end use(s) : No further relevant information available.

SECTION 8: Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see section 7.
- 8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace:

56-81-5 glycerol ($\leq 1\%$)

WEL (Great Britain)	Long-term value: 10 mg/m ³
MAK (Switzerland)	Short-term value: 100 e mg/m ³ Long-term value: 50 e mg/m ³ SSc;

- Additional information:
As a basis for the production of this document, the most current valid lists were used.
- 8.2 Exposure controls
- Personal protective equipment:
- General protective and hygienic measures: Wash hands before breaks and at the end of work.
- Respiratory protection: Not required.
- Protection of hands: Not required.
- Gloves material :
The selection of suitable gloves does not only depend on the material, but also on further marks of quality which may vary from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked before use.

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· **Eye protection:** Goggles recommended during refilling

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· Form:	Liquid
· Colour:	According to product specification
· Odour:	Characteristic
· Odour threshold:	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not applicable.

· **Ignition temperature:** Not applicable.

· **Decomposition temperature:** Not determined.

· **Self-igniting:** Product is not self igniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapour pressure:** Not determined.

· **Density:** Not determined.

· **Relative density :** Not determined.

· **Vapour density :** Not determined.

· **Evaporation rate :** Not determined.

· **Solubility in / Miscibility with water:**

Not miscible or difficult to mix.

· **Segregation coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

· Dynamic:	Not determined.
· Kinematic:	Not determined.

· **9.2 Other information :** No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity**

· **10.2 Chemical stability**

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

· **10.3 Possibility of hazardous reactions :** No dangerous reactions known.

· **10.4 Conditions to avoid :** No further relevant information available.

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- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **On the skin:** No irritant effect.
- **On the eyes:** No irritant effect.
- **Sensitisation:** No sensitising effects known.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability :** No further relevant information available.
- **12.3 Bioaccumulative potential :** No further relevant information available.
- **12.4 Mobility in soil :** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects :** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation :**



Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|---------------------------------------|---|
| · 14.1 UN-Number | |
| · ADR, ADN, IMDG, IATA | Not classified as hazardous for transport |
| · 14.2 UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | Not classified as hazardous for transport |

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· 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class	<i>Not classified as hazardous for transport</i>
· 14.4 Packing group · ADR, IMDG, IATA	<i>Not classified as hazardous for transport</i>
· 14.5 Environmental hazards: · Marine pollutant:	<i>No</i>
· 14.6 Special precautions for user	<i>Not applicable.</i>
· 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	<i>Not applicable.</i>
· UN "Model Regulation":	<i>-</i>

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **15.2 Chemical safety assessment:** *A Chemical Safety Assessment has not been carried out.*

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**
H319 Causes serious eye irritation.
R36 Irritating to eyes.
- **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2