B. Suico St., Tingub, Mandaue City 6014

Trunklines: GLOBE: (032) 420-6900 PLDT: (032) 260-6910 Website: www.ipi.ph Email: inquiry@ipi.ph

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SAFETY DATA SHEET

Section 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Identity OMEGA PAIN KILLER CREAM
Company Name International Pharmaceuticals, Inc.

Company Address Golam Drive, Pope John Paul II Avenue, Kasambagan,

Cebu City, Cebu, Philippines

Telephone Number +63 32 412-6900 / +63 32 260-6910

Intended Use As counterirritant (pharmaceutical) product

Section 2. HAZARD(S) IDENTIFICATION

GHS Classification

Skin corrosion/ irritation Category 2
Serious eye damage/ Category 2A

eye irritation

Acute toxicity (oral)

Specific target organ

Toxicity, single exposure

Category 4

Category 2

GHS Label Element

Hazard Pictogram(s)



Signal Word(s) Warning

Hazard Statement(s) Harmful if swallowed (H302)
Causes skin irritation (H315)

Causes serious eye irritation (H319) May cause damage to organs (H371)

Precautionary Statement(s)

Prevention Do not breathe dust/fume/gas/mist/vapors/spray. (P260)

Wash hands thoroughly after handling. (P264)

Do not eat, drink or smoke when using this product. (P270) Wear protective gloves/protective clothing/eye protection/face

protection. (P280)

Response IF SWALLOWED: call a POISON CENTER or

doctor/physician IF you feel unwell. (P301+ P312)

Rinse mouth. (P330)

IF exposed or if you feel unwell: call a POISON CENTER or

doctor/ physician. (P309+P311)

IF ON SKIN: wash with plenty of soap and water.

(P302+P352)

IF SKIN irritation occurs: Get medical advice/attention.

(P332+P313)

Take off contaminated clothing and wash before reuse. (P362)

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue

rinsing. (P305+P351+P338)

IF eye irritation persists: Get medical advice/attention.

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(P337+P313)

Storage Store locked up. (P405)

Disposal Dispose of contents/container to an approved waste disposal

plant. (P501)

Other hazards None

Section 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Identity Mixture

Ingredients	CAS Number	EC Number	Concentration
Camphor	76-22-2	200-945-0	40 %
Menthol	1490-04-6	201-939-0	10.0 %
Methyl Salicylate	119-36-8	204-317-7	30.0 %
Cetyl Alcohol	36653-82-4	253-149-0	0.5 – 1.0%
Stearic Acid	57-11-4	200-313-4	1.0 – 2.5%
Triethanolamine	102-71-6	203-049-8	1.0 – 3.0%
* Other Non-Hazardous Ingredients	N/A	N/A	≤ 50%

In accordance with the paragraph (i) of Sec. 1910.1200, the specific chemical identity and/or exact percentage (concentration) of mixture has been withheld as a trade secret.

Section 4. FIRST AID MEASURES

Necessary first-aid measures

Inhalation Overexposure is most likely to occur dealing with large

quantities and in an enclosed space with inadequate ventilation. Remove to fresh air. Allow patient to rest in a well-

ventilated area. Seek medical attention.

Skin Contact If irritation occurs, discontinue use. Wipe off and wash

exposed area with soap and water. Get medical attention if

irritation develops.

Eye Contact Check for and remove any contact lenses. Rinse immediately

with clean water for at least 15 minutes. Seek medical

attention.

Ingestion Do not induce vomiting. Wash mouth with water. Seek medical

attention immediately if symptoms persist.

Most important symptoms

/ effects, both acute and

delayed

No information available.

Note(s) to physician Treat symptomatically.

Section 5. FIRE FIGHTING MEASURES

Suitable extinguishing

media

Use dry chemical powder, water spray, fog or foam.

Unsuitable extinguishing

media

High volume water jet

Specific hazards arising Irritating and highly toxic gases may be generated by thermal

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^{*} Unidentified ingredients are not considered hazardous under the Federal Hazard Communication Standard (28 CFR Sec. 1910.1200)



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from the chemical decomposition or combustion. Do not breathe fumes. Keep

product and empty container away from sources of ignition.

Hazardous combustion

products

Special protective actions

for fire-fighters

Carbon oxides

Fire fighters should wear positive pressure self-contained

breathing apparatus.

Specific extinguishing

methods

Cool containers exposed to flame with water spray. Spray

extinguishing media directly into base of fire.

Section 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Non-emergency personnel

Before cleaning any spill or leak, individuals involved in spill cleanup must wear appropriate Personal Protective

Equipment (i.e. goggles, gloves). Remove spilled material with absorbent material (l.e. sand, earth, diatomaceous earth, vermiculite) and place into appropriate closed container(s) for

disposal.

Emergency responders Before cleaning any spill or leak, individuals involved in spill

cleanup must wear appropriate Personal Protective Equipment. Deny entry to all unprotected individuals. Maximize ventilation (open doors and windows).

Environmental precautions

Keep spills and cleaning runoffs out of nearby sewers and

open bodies of water.

Methods and materials for containment and cleaning up

Dike and contain spill with inert material (e.g. sand or earth). Transfer soiled material to containers for recovery or disposal and solid diking material to separate containers for proper disposal. Dispose of properly in accordance with local or national regulations. Wash all affected area and outside of container with plenty of warm water and soap. Remove any contaminated clothing and wash thoroughly before reuse.

Section 7. HANDLING AND STORAGE

Precautions for safe handling

No special control measures required for normal handling. Normal room ventilation is expected to be adequate for routine handling. Follow good industrial practice as to housekeeping, personal hygiene and avoidance of prolonged or repeated contact with the skin or eyes. Keep away from fire, sparks

and heated surfaces.

Conditions for safe

storage

Keep away from heat and sources of ignition. Keep in a cool, well-ventilated place. Keep away from oxidizing agents. Keep out of reach of children. Keep container tightly closed. Store in suitable labeled containers at temperatures not exceeding

30°C.

Materials to avoid No special restrictions on storage with other products.

Section 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

If a component is disclosed in Section 3. (Composition/Information on Ingredients) but does not

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appear in the table below, an occupational exposure limit or recorded limit is not available for the component.

Chamical Name	Exposure Limits			
Chemical Name	OSHA [A]	NIOSH [B]		
Camphor	PEL-TWA: 2 mg/m³	REL-TWA: 2 mg/m³		
Triethanolamine	CAPEL-TWA: 5 mg/m³			

[[]A] Occupational Safety and Health Administration (OSHA)

Appropriate engineering controls

Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value. Ensure that eyewash stations and safety showers are proximal to the work-station location.

Individual protection measures

Eye / face protection Not required under normal conditions of use. Wear safety

glasses or goggles if eye contact is possible.

Hand protection Not required for the normal use of this product. Wear gloves

> when working with large quantities. The glove material has to be impermeable and resistant to the product such as nitrile rubber,

neoprene gloves, butyl rubber or natural rubber gloves.

Skin / body protection Not required for the normal use of this product. Use protective

clothing (lab coats, disposable coveralls, etc.) in both production

and laboratory areas.

Not required for the normal use of this product. If the applicable Respiratory protection

> Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control

exposures to below the OEL.

Thermal hazards No special protective equipment required.

Hygiene measures General industrial hygiene practice.

Section 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, White cream

color, etc.)

Odor

Characteristic Odor threshold Not determined.

рΗ 8.02

Melting point / freezing point Initial boiling point and

boiling range

Not determined.

Not determined.

Flash point Not determined. Evaporation rate Not determined. Flammability (solid, gas) Not determined.

Upper / lower flammability or

explosive limits

Not determined.

Vapor pressure Not determined. Vapor density Not determined.

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[[]B] The National Institute of Occupational Safety and Health (NIOSH)

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Specific gravity 1.0465

Solubility(ies) Not determined. Partition coefficient Not determined.

(n-octanol / water)

Auto-ignition temperature Not determined. Decomposition temperature Not determined. 24,000 cps Viscosity

Section 10. STABILITY AND REACTIVITY

Reactivity Stable under recommended storage conditions. Chemical stability No decomposition if stored and applied as directed.

Possibility of hazardous

reactions

No hazards to be specially mentioned.

Conditions to avoid Avoid contact with sparks, flame and heat.

Incompatible materials Avoid contact with strong oxidizing agents and avoid hot work

and sources of ignition on or near empty containers

Hazardous decomposition

products

CO, CO₂ smoke and unidentified organic compounds may be

formed during combustion.

Section 11. TOXICOLOGICAL INFORMATION

This product has not been tested on animals to obtain toxicological data. There are toxicology data for the components of this product, which are found in the scientific literature. These data have not been presented in this document.

Information of the likely routes of exposure Potential health effects

Inhalation, eye contact, skin contact, ingestion

Inhalation Health injuries are not known or expected under normal use.

Skin contact Causes skin irritation. Not a skin sensitizer.

Harmful if swallowed. Ingestion

Not an expected route of exposure; however, direct contact Eye contact

can cause serious eye irritation

Experience with human exposure

Inhalation No symptoms known or expected under normal exposure. Skin contact No symptoms known or expected under normal exposure. Ingestion No symptoms known or expected under normal exposure. Eye contact No symptoms known or expected under normal exposure.

Acute toxicity

Product Oral toxicity No data available.

> No data available. Inhalation toxicity Dermal toxicity No data available.

Ingredient(s) **Menthol**

> Oral toxicity LD₅₀ (rat): 3,180 mg/kg Dermal toxicity LD₅₀ (rabbit): >5000 mg/kg Inhalation LD₅₀ (rat): 5,289 mg/m³/ 4h

Camphor

Oral toxicity LD₅₀ (mouse): 1310 mg/kg

No data available. Dermal toxicity Inhalation No data available.

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Methyl salicylate

Oral toxicity LD₅₀ (mouse): 1,110 mg/kg

LD₅₀ (rat): 887 mg/kg LD₅₀ (rabbit): 1300 mg/kg LD₅₀ (child): 228 mg/kg

LD₅₀ (adult human): 506 mg/kg

Dermal toxicity No data available. Inhalation No data available.

Cetyl Alcohol

Oral toxicity LD₅₀ (rat): 5 g/kg

LD₅₀ (mouse): 3200 mg/kg

Dermal toxicity LD₅₀ (guinea pig): < 10 g/kg

Inhalation No data available.

Triethanolamine

Oral toxicity LD₅₀ (mouse): 7400 mg/kg

LD₅₀ (rat): 8.0 g/kg

LD₅₀ (guinea pig): 5300 mg/kg

Dermal toxicity LD₅₀ (rabbit): >20,000 mg/kg

Inhalation No data available.

Stearic Acid

No data available.

Skin corrosion / irritation

Product

Ingredient(s)

No data available.

Menthol

Causes skin irritation

Camphor

No data available.

Methyl salicylate

No data available.

Cetyl Alcohol

Skin - rabbit

Result: No skin irritation - 4 h (OECD

Test Guideline 404)

Triethanolamine

No data available.

Stearic Acid

May cause slight skin irritation.

Serious eye damage / irritation

Product

No data available.

Ingredient(s)

Menthol

Causes serious eye irritation

Camphor

No data available.

Methyl salicylate

No data available.

Cetyl Alcohol

Eyes - rabbit

Result: No eye irritation - 72 h (OECD Test Guideline

405)

• Triethanolamine

Causes eye irritation.

Stearic acid

May cause eye irritation

Respiratory or skin sensitization

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Product Ingredient(s) No data available.

Menthol

Shall not be classified as a respiratory or skin sensitizer

Camphor

No data available.

Methyl salicylate

No data available.

Cetyl Alcohol

Maximization Test - guinea pig

Result: Does not cause skin sensitization. (OECD

Test Guideline 406) **Triethanolamine**

May cause skin sensitization.

Stearic Acid

No data available.

Germ cell mutagenicity

Ingredient(s)

Product

No data available.

Menthol

Shall not be classified as germ cell mutagenic

Camphor

No data available.

Methyl salicylate

No data available.

Cetyl Alcohol

Not mutagenic in Ames Test.

Ames test S. typhimurium

Result: negative

Triethanolamine

No data available.

Stearic Acid

No data available.

Carcinogenicity

Product

No data available.

Ingredient(s)

Menthol

Shall not be classified as carcinogenic

Camphor

Not listed as a carcinogen

Methyl salicylate

Not listed as a carcinogen

Cetyl Alcohol

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Triethanolamine

Not listed as a carcinogen.

Stearic Acid

Menthol

Not listed as a carcinogen

Reproductive toxicity

<u>Product</u>

No data available.

Ingredient(s)

Shall not be classified as a reproductive toxicant

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Camphor

No data available.

Methyl salicylate

No data available.

Cetyl Alcohol

No data available.

Triethanolamine

No data available.

Stearic Acid

No data available.

STOT-single exposure

Product

No data available.

Ingredient(s)

Menthol

Shall not be classified as a specific target organ toxicant (single exposure).

Camphor

Respiratory system

Methyl salicylate

No data available.

Cetyl Alcohol

No data available.

Triethanolamine

No data available.

Stearic Acid

No data available.

STOT-repeated exposure

Product

No data available.

Ingredient(s)

Menthol

Shall not be classified as a specific target organ toxicant (repeated exposure).

Camphor

None known

Methyl salicylate

No data available.

Cetyl Alcohol

No data available.

Triethanolamine

No data available.

Stearic Acid

No data available.

Aspiration hazard

Product

No data available.

Ingredient(s)

Menthol

Shall not be classified as presenting an aspiration hazard.

Camphor

No data available

Methyl salicylate

No data available.

Cetvl Alcohol

No data available.

Triethanolamine

No data available.

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Stearic Acid

No data available.

Section 12. ECOLOGICAL INFORMATION

Ecotoxicity

Environmental effects

No data available.

Toxicity to fish

Product No data available.
Ingredient(s) • Menthol

Aquatic toxicity (acute) LD₅₀: 22.3 mg/l Exposure time 96 hours

Camphor

Aquatic toxicity (acute) LD₅₀: 36 mg/l Exposure time 96 hours

• Methyl salicylate

No data available.

Cetyl Alcohol

Aquatic toxicity (acute) LC₅₀: >0.4 mg/l (rainbow trout)

Exposure time 96 hours

• Triethanolamine

Aquatic toxicity (acute) LC₅₀: 5600 mg/l

(fathead minnow)

Exposure time 96 hours

• Stearic Acid

No data available.

Toxicity to daphnia and other aquatic invertebrates

Product No data available.

Ingredient(s)

Menthol

Aquatic toxicity (acute) EC₅₀: 26.6 mg/l Exposure time 48 hours

Camphor

No data available.

Methyl salicylate

No data available.

Cetyl Alcohol

No data available.

Triethanolamine

No data available.

Stearic Acid

No data available.

Toxicity to algae

Product No data available.

Ingredient(s)

Menthol

Aquatic toxicity (acute) ErC₅₀: 16.2 mg/l Exposure time 72 hours

Camphor

No data available.

Methyl salicylate

No data available.

Cetyl Alcohol

Aquatic toxicity (acute) EC₅₀: 1.000 mg/l

Exposure time 96 hours

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Triethanolamine

No data available.

• Stearic Acid

No data available.

Persistence and degradability

Product No data available.

Ingredient(s)

Menthol

Theoretical Oxygen Demand 2.97 g/g
Theoretical Carbon Dioxide 2.816 mg/mg

Camphor

No data available

Methyl salicylate

No data available.

Cetyl Alcohol

Aerobic Exposure time 28 d Result: 82.4 % Readily biodegradable.

(OECD Test Guideline 301B)

Triethanolamine

No data available.

Stearic Acid

No data available.

Bioaccumulative potential

Product No data available.

Ingredient(s)

Menthol

Does not significantly accumulate in organisms. n-octanol/water (log KOW) 3.4 (pH value:

7.2, 37 °C)

BCF ≥0.5 – ≤15

(ECHA)

Camphor

No data available.

Methyl salicylate

No data available.

Cetyl Alcohol

Leuciscus idus melanotus 3 d 48 µg/l Bioconcentration factor 1.230

Triethanolamine

No data available.

Stearic Acid

No data available.

Mobility in soil

<u>Product</u> No data available. Ingredient(s) No data available.

Other adverse effects

<u>Product</u> No data available. <u>Ingredient(s)</u> No data available.

Section 13. DISPOSAL CONSIDERATIONS

Disposal Methods

The product should not be allowed to enter drains, water courses or the soil. Where possible recycling is preferred to disposal or incineration. If recycling is not practicable, dispose of in compliance with local regulations. Dispose of wastes in an approved waste disposal facility.

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Disposal considerations Dispose of as unused product. Empty containers

should be taken to an approved waste handling site for recycling or disposal. Observe all local and national regulations when disposing of this product.

Do not reuse empty containers.

Section 14. TRANSPORT INFORMATION

Transport labeling: The shipper/consignor/sender is responsible to ensure that the packaging, labeling, and markings are in compliance with the selected mode of transport.

Land transport

UN Number Not regulated as dangerous goods.
UN proper shipping Not regulated as dangerous goods.

name

Transport hazard Not regulated as dangerous goods.

class(es)

Packing group Not regulated as dangerous goods. Environmental hazard Not regulated as dangerous goods.

Sea transport

UN Number Not regulated as dangerous goods.
UN proper shipping Not regulated as dangerous goods.

name

Transport hazard Not regulated as dangerous goods.

class(es)

Packing group Not regulated as dangerous goods. Environmental hazard Not regulated as dangerous goods.

Air transport

UN Number Not regulated as dangerous goods.
UN proper shipping Not regulated as dangerous goods.
name

Transport hazard

class(es)

Packing group Not regulated as dangerous goods. Environmental hazard Not regulated as dangerous goods.

Section 15. REGULATORY INFORMATION

Not regulated as dangerous goods.

The regulatory data in this section is not intended to be all-inclusive, only selected regulations are represented.

International Inventories

Country / Region	on Inventory Name	On Inventory (Yes / No)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes

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Korea	Act on the Registration and Evaluation of Chemicals (REACH)	No
Korea New Zealand	Korea Existing Chemicals Inventory (KECI) New Zealand Inventory of Chemicals (NZIoC)	No Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan United States	Taiwan Chemical Substance Inventory (TCSI) Toxic Substances Control Act (TSCA) Inventory	Yes Yes

^{*}A "**Yes**" indicates that all components of this product comply with the inventory requirements administered by the governing country(s). A "**No**" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s). Certain restrictions may apply.

This SDS has been prepared in accordance to the UN Globally Harmonized System and the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200. While the finished product is not considered hazardous as defined in 29 CFR 1910.1200 (d), this Safety Data Sheet contains valuable information critical to the safe handling and proper use of the product.

Section 16. OTHER INFORMATION

Further Information

Abbreviations:

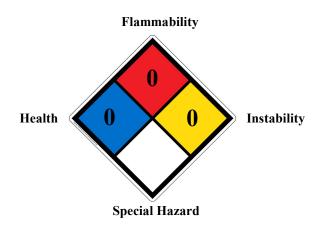
PEL – Permissible Exposure Limit TWA - Time Weighted Average

PEL-TWA – Permissible Exposure Limit – 8-hour Time Weighted Average REL-TWA – Recommended Exposure Limit – Time Weighted Average CAPEL-TWA – California Permissible Exposure Limit – Time Weighted

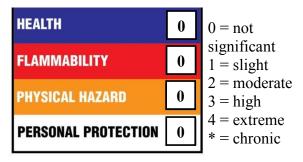
Average

IDLH - Immediately Dangerous to Life or Health

NFPA



HMIS



Data Publicly available information.

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Issued Date 8 September 2022

Prepared by Product Research and Development Department

International Pharmaceuticals Inc.

LRU/JBA/CJS

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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