



SAFETY DATA SHEET

Revision date: 02-Nov-2018

Version: 2.0

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: ChapStick Key Lime (KOBO Color, Paraben removal)

Trade Name: ChapStick
Compound Number: WH-1749-0003
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Consumer healthcare product used for skin care

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
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Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Skin Corrosion/Irritation: Category 3
Skin Sensitization: Category 1B

Label Elements

Signal Word: Warning
Hazard Statements: H316 - Causes mild skin irritation
H317 - May cause an allergic skin reaction

Precautionary Statements:

P272 - Contaminated work clothing must not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P363 - Wash contaminated clothing before reuse
P501 - Dispose of contents/container in accordance with all local and national regulations

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Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Butylated hydroxytoluene	128-37-0	204-881-4	Not Listed	*
Cetyl alcohol	36653-82-4	253-149-0	Not Listed	*
Flavor (H315) (H317) (H319) (H304) (H226)	Not Assigned	Not Listed	Not Listed	3.47
Light mineral oil (liquid paraffin)	8042-47-5	232-455-8	Not Listed	*
Paraffin	8002-74-2	232-315-6	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
White petrolatum	8009-03-8	232-373-2	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Arachidyl propionate	65591-14-2	265-839-9	Not Listed	*
Beeswax	8012-89-3	232-383-7	Not Listed	*
Bis-Diglyceryl Polyacyladipate-2	82249-33-0	Not Listed	Not Listed	*
Caprylic/capric triglyceride	65381-09-1	265-724-3	Not Listed	*
Carnauba wax	8015-86-9	232-399-4	Not Listed	*
FD&C Blue no. 1 aluminum lake	68921-42-6	272-939-6	Not Listed	*
FD&C Yellow 5 Lake	12225-21-7	235-428-9	Not Listed	*
Isopropyl myristate	110-27-0	203-751-4	Not Listed	*
Isopropyl titanium triisostearate	61417-49-0	262-774-8	Not Listed	*
Lecithin	8002-43-5	232-307-2	Not Listed	*
Octyldodecanol	5333-42-6	226-242-9	Not Listed	*
Phenyl trimethicone	2116-84-9	218-320-6	Not Listed	*
Saccharin	81-07-2	201-321-0	Not Listed	*
Synthetic wax	68527-08-2	Not Listed	Not Listed	*
Triacetin	102-76-1	203-051-9	Not Listed	*

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Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: No data available

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

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Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Consumer healthcare product used for skin care

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Butylated hydroxytoluene

ACGIH Threshold Limit Value (TWA)	2 mg/m ³
Australia TWA	10 mg/m ³
Austria OEL - MAKs	10 mg/m ³
Belgium OEL - TWA	2 mg/m ³
Bulgaria OEL - TWA	10 mg/m ³
Denmark OEL - TWA	10 mg/m ³
Finland OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Germany - TRGS 900 - TWAs	10 mg/m ³
Germany (DFG) - MAK	10 mg/m ³ can occur as vapor and aerosol at the same time
Greece OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
Portugal OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL -TWAs	10 mg/m ³

Cetyl alcohol

Germany - TRGS 900 - TWAs	20 ppm
	200 mg/m ³

Light mineral oil (liquid paraffin)

Germany - TRGS 900 - TWAs	5 mg/m ³
Germany (DFG) - MAK	5 mg/m ³

Paraffin

ACGIH Threshold Limit Value (TWA)	2 mg/m ³
Australia TWA	2 mg/m ³
Belgium OEL - TWA	2 mg/m ³
Denmark OEL - TWA	2 mg/m ³
Estonia OEL - TWA	2 mg/m ³
Finland OEL - TWA	1 mg/m ³
France OEL - TWA	2 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Greece OEL - TWA	2 mg/m ³
Ireland OEL - TWAs	2 mg/m ³
Poland OEL - TWA	2 mg/m ³
Portugal OEL - TWA	2 mg/m ³
Romania OEL - TWA	2 mg/m ³
Spain OEL - TWA	2 mg/m ³
Switzerland OEL -TWAs	2 mg/m ³
Vietnam OEL - TWAs	1 mg/m ³
 Titanium dioxide	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Austria OEL - MAKs	5 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Denmark OEL - TWA	6 mg/m ³
Estonia OEL - TWA	5 mg/m ³
France OEL - TWA	10 mg/m ³
Greece OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	5 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
Ireland OEL - TWAs	4 mg/m ³
Latvia OEL - TWA	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
OSHA - Final PELS - TWAs:	15 mg/m ³
Poland OEL - TWA	10.0 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³
Russia OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Sweden OEL - TWAs	5 mg/m ³
Switzerland OEL -TWAs	3 mg/m ³
Vietnam OEL - TWAs	6 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³
 White petrolatum	
ACGIH Threshold Limit Value (TWA)	5 mg/m ³ (oil mist, mineral)
ACGIH Threshold Limit Value (STEL)	10 mg/m ³ (oil mist, mineral)
 Exposure Controls	
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eyes:	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin:	Not required for the normal use of this product. Wear protective clothing when working with large quantities.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection: Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Waxy Solid	Color:	Green
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
pH:	No data available.		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
Carnauba wax			
No data available			
Isopropyl myristate			
No data available			
Arachidyl propionate			
No data available			
Octyldodecanol			
No data available			
Phenyl trimethicone			
No data available			
Beeswax			
No data available			
Saccharin			
No data available			
Bis-Diglyceryl Polyacyladipate-2			
No data available			
Paraffin			
No data available			
Caprylic/capric triglyceride			
No data available			
FD&C Blue no. 1 aluminum lake			
No data available			
Triacetin			
No data available			
Butylated hydroxytoluene			
No data available			
Titanium dioxide			
No data available			
Cetyl alcohol			
No data available			
Light mineral oil (liquid paraffin)			
No data available			
Synthetic wax			
No data available			
Isopropyl titanium triisostearate			

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9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

FD&C Yellow 5 Lake

No data available

White petrolatum

No data available

Lecithin

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: May cause eye irritation May cause skin irritation. (based on components)

Acute Toxicity: (Species, Route, End Point, Dose)

Isopropyl myristate

Mouse Oral LD50 49,700 mg/kg

Rabbit Dermal LD50 5000 mg/kg

Bis-Diglyceryl Polyacyladipate-2

Rat Dermal LD50 > 2000 mg/kg

Rat Oral LD50 > 2000mg/kg

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11. TOXICOLOGICAL INFORMATION

Paraffin

Rat Oral LD50 >3750 mg/kg
Rabbit Dermal LD50 >3600mg/kg

Triacetin

Rat Oral LD 50 3000 mg/kg
Mouse Oral LD 50 1100mg/kg

Butylated hydroxytoluene

Rat Oral LD50 1700 mg/kg
Mouse Oral LD50 650 mg/kg
Rat Oral LD50 890 mg/kg
Mouse Intraperitoneal LD 50 138 mg/kg

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD50 50 mg/kg

Cetyl alcohol

Rat Oral LD50 5000 mg/kg
Rabbit Dermal LD50 > 2,600 mg/kg
Mouse Oral LD50 3200 mg/kg

Light mineral oil (liquid paraffin)

Rat Oral LD50 > 5000 mg/kg

Lecithin

Rat Oral LD50 > 8 ml/kg

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Bis-Diglyceryl Polyacyladipate-2

Skin Irritation Rabbit Non-irritating
Skin Irritation Guinea Pig Slight
Skin Sensitization - GPMT Guinea Pig Negative
Eye Irritation Rabbit Non-irritating

Paraffin

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Butylated hydroxytoluene

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Moderate

Light mineral oil (liquid paraffin)

Eye Irritation Rabbit Non-irritating

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11. TOXICOLOGICAL INFORMATION

Skin Irritation Rabbit Non-irritating

Skin Sensitization - GPMT Guinea Pig Negative

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Butylated hydroxytoluene

4 Week(s) Rat Oral 5185 mg/kg LOAEL Liver

4 Day(s) Mouse Oral 2000 mg/kg LOAEL Liver, Kidney, Ureter, Bladder

Light mineral oil (liquid paraffin)

90 Day(s) Rat Oral 1800 mg/kg/day NOAEL Liver

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Butylated hydroxytoluene

Embryo / Fetal Development Rat Oral 6 g/kg LOEL Teratogenic,

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Light mineral oil (liquid paraffin)

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative

In Vitro Mammalian Cell Mutagenicity Mouse Lymphoma Negative

Carcinogen Status:

See below

Saccharin

IARC: Group 3 (Not Classifiable)

Butylated hydroxytoluene

IARC: Group 3 (Not Classifiable)

Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Light mineral oil (liquid paraffin)

Lepomis macrochirus (Bluegill Sunfish) OECD LC50 96 Hours > 10000 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Arachidyl propionate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	265-839-9

Beeswax

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-383-7

Bis-Diglyceryl Polyacyladipate-2

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

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Butylated hydroxytoluene

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-881-4

Caprylic/capric triglyceride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	265-724-3

Carnauba wax

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-399-4

Cetyl alcohol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	253-149-0

FD&C Blue no. 1 aluminum lake

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	272-939-6

FD&C Yellow 5 Lake

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	235-428-9

Flavor (H315) (H317) (H319) (H304) (H226)

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Isopropyl myristate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

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Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	203-751-4
Isopropyl titanium triisostearate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	262-774-8
Lecithin	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-307-2
Light mineral oil (liquid paraffin)	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-455-8
Octyldodecanol	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	226-242-9
Paraffin	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-315-6
Phenyl trimethicone	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	218-320-6
Saccharin	
CERCLA/SARA 313 Emission reporting	1.0 %
California Proposition 65	Not Listed

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Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-321-0
Synthetic wax	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
Titanium dioxide	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen 9/2/2011 airborne, unbound particles of respirable size
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5
Triacetin	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	203-051-9
White petrolatum	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 28.
REACH - Carcinogens Category 2:	Present
EU EINECS/ELINCS List	232-373-2

Additional Information:

White petrolatum is not classified as a carcinogen. Nota N applies since the full refining history is known and it can be shown that the substances from which the petroleum jelly was produced are not a carcinogen.

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Skin corrosion/irritation-Cat.2; H315 - Causes skin irritation
Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
Aspiration hazard-Cat.1; H304 - May be fatal if swallowed and enters airways
Flammable liquids-Cat.3; H226 - Flammable liquid and vapor

Data Sources:

Pfizer proprietary drug development information. Safety data sheets for individual ingredients. Publicly available toxicity information.

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Reasons for Revision: Updated Section 2 - Hazard Identification.

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Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet



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Product Identifier

Material Name: ChapStick Flava Craze Grape Craze

Trade Name: ChapStick
Compound Number: WH-0739-0001
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Consumer healthcare product used for skin care

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
1 Giralda Farms
Madison, NJ 07940

Pfizer Ltd
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not required
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Mineral oil	8012-95-1	232-384-2	Not Listed	*
Paraffin	8002-74-2	232-315-6	Not Listed	*
White petrolatum	8009-03-8	232-373-2	Not Listed	44

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Arachidyl propionate	65591-14-2	265-839-9	Not Listed	*
Beeswax	8012-89-3	232-383-7	Not Listed	*
Carnauba wax	8015-86-9	232-399-4	Not Listed	*
Cetyl alcohol	36653-82-4	253-149-0	Not Listed	*
D&C Red No. 6 Barium Lake	17852-98-1	241-806-4	Not Listed	*
FD&C Blue no. 1 aluminum lake	68921-42-6	272-939-6	Not Listed	*
Flavoring agents	Not assigned	Not Listed	Not Listed	*
Isopropyl lanolate	63393-93-1	264-119-1	Not Listed	*
Isopropyl myristate	110-27-0	203-751-4	Not Listed	*
Lanolin	8006-54-0	232-348-6	Not Listed	*
Methylparaben	99-76-3	202-785-7	Not Listed	*
Octyldodecanol	5333-42-6	226-242-9	Not Listed	*
Phenyl trimethicone	2116-84-9	218-320-6	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	*
Saccharin	81-07-2	201-321-0	Not Listed	*

Additional Information:

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. * Proprietary

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact:

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact:

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion:

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation:

Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure:

No data available

Medical Conditions Aggravated by Exposure:

None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician:

None

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5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Consumer healthcare product used for skin care

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Cetyl alcohol

Germany - TRGS 900 - TWAs 20 ppm
200 mg/m³

D&C Red No. 6 Barium Lake

ACGIH Threshold Limit Value (TWA) 0.5 mg/m³

Mineral oil

ACGIH Threshold Limit Value (TWA) 5 mg/m³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia TWA	5 mg/m ³
Belgium OEL - TWA	5 mg/m ³
Bulgaria OEL - TWA	5.0 mg/m ³
Czech Republic OEL - TWA	5 mg/m ³
Denmark OEL - TWA	1 mg/m ³
Finland OEL - TWA	5 mg/m ³
Greece OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	1 mg/m ³
Netherlands OEL - TWA	5 mg/m ³
OSHA - Final PELS - TWAs:	5 mg/m ³
Poland OEL - TWA	5 mg/m ³
Portugal OEL - TWA	5 mg/m ³
Romania OEL - TWA	5 mg/m ³
Slovakia OEL - TWA	5 ppm 1 mg/m ³ 5 mg/m ³
Spain OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	1 mg/m ³
Vietnam OEL - TWAs	5 mg/m ³

Paraffin

ACGIH Threshold Limit Value (TWA)	2 mg/m ³
Australia TWA	2 mg/m ³
Belgium OEL - TWA	2 mg/m ³
Denmark OEL - TWA	2 mg/m ³
Estonia OEL - TWA	2 mg/m ³
Finland OEL - TWA	1 mg/m ³
France OEL - TWA	2 mg/m ³
Greece OEL - TWA	2 mg/m ³
Ireland OEL - TWAs	2 mg/m ³
Poland OEL - TWA	2 mg/m ³
Portugal OEL - TWA	2 mg/m ³
Romania OEL - TWA	2 mg/m ³
Spain OEL - TWA	2 mg/m ³
Switzerland OEL -TWAs	2 mg/m ³
Vietnam OEL - TWAs	1 mg/m ³

White petrolatum

ACGIH Threshold Limit Value (TWA)	5 mg/m ³ (oil mist, mineral)
ACGIH Threshold Limit Value (STEL)	10 mg/m ³ (oil mist, mineral)

Exposure Controls

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Wear protective gloves when working with large quantities.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Wear protective clothing when working with large quantities.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Waxy Solid	Color:	Purple
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
pH:	No data available.		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
Carnauba wax			
No data available			
Cetyl alcohol			
No data available			
Isopropyl myristate			
No data available			
Methylparaben			
No data available			
Propylparaben			
No data available			
Arachidyl propionate			
No data available			
D&C Red No. 6 Barium Lake			
No data available			
Isopropyl lanolate			
No data available			
Octyldodecanol			
No data available			
Paraffin			
No data available			
Phenyl trimethicone			
No data available			
White petrolatum			
No data available			
FD&C Blue no. 1 aluminum lake			
No data available			
Beeswax			
No data available			
Mineral oil			
No data available			
Saccharin			
No data available			
Lanolin			
No data available			
Flavoring agents			
No data available			
Decomposition Temperature (°C):	No data available.		
Evaporation Rate (Gram/s):	No data available		
Vapor Pressure (kPa):	No data available		
Vapor Density (g/ml):	No data available		

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Relative Density: No data available
Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: May cause eye irritation May cause skin irritation. (based on components)

Acute Toxicity: (Species, Route, End Point, Dose)

Cetyl alcohol

Rat Oral LD50 5000 mg/kg
Rabbit Dermal LD50 > 2,600 mg/kg
Mouse Oral LD50 3200 mg/kg

Isopropyl myristate

Mouse Oral LD50 49,700 mg/kg
Rabbit Dermal LD50 5000 mg/kg

Propylparaben

Mouse Oral LD 50 6332 mg/kg
Mouse Sub-tenon injection (eye) LD 50 200 mg/kg

Paraffin

Rat Oral LD50 >3750 mg/kg
Rabbit Dermal LD50 >3600mg/kg

Lanolin

Rat Oral LD50 >5000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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11. TOXICOLOGICAL INFORMATION

Irritation / Sensitization: (Study Type, Species, Severity)

Isopropyl lanolate

• Skin Irritation Rabbit Mild
• Eye Irritation Rabbit Mild

Paraffin

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Mineral oil

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Propylparaben

3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system
 4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Lanolin

Fertility and Embryonic Development Rabbit Oral 200 mg/kg/day LOAEL Maternal toxicity, Not teratogenic

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Saccharin

IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Arachidyl propionate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	265-839-9

Beeswax

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-383-7

Carnauba wax

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-399-4

Cetyl alcohol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

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15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	253-149-0
D&C Red No. 6 Barium Lake	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	241-806-4
FD&C Blue no. 1 aluminum lake	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	272-939-6
Flavoring agents	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
Isopropyl lanolate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	264-119-1
Isopropyl myristate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	203-751-4
Lanolin	
CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 10000 lb upper threshold TPQ = 500 lb lower threshold TPQ
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-348-6
Methylparaben	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7

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15. REGULATORY INFORMATION

Mineral oil

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-384-2

Octyldodecanol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	226-242-9

Paraffin

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-315-6

Phenyl trimethicone

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	218-320-6

Propylparaben

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-307-7

Saccharin

CERCLA/SARA 313 Emission reporting	1.0 %
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-321-0

White petrolatum

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 28.
REACH - Carcinogens Category 2:	Present
EU EINECS/ELINCS List	232-373-2

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15. REGULATORY INFORMATION

Additional Information: White petrolatum is not classified as a carcinogen. Nota N applies since the full refining history is known and it can be shown that the substances from which the petroleum jelly was produced are not a carcinogen.

16. OTHER INFORMATION

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 16 - Other Information.

Revision date: 13-Feb-2017

Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet



SAFETY DATA SHEET

1. Identification

Product identifier ChapStick DUO Cotton Candy

Other means of identification

Product code WH-1827-0001

Synonyms WH-1827-0001

Recommended use Consumer Healthcare Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

COMPANY NAME GlaxoSmithKline US

Address: 5 Moore Drive
Research Triangle Park, NC 27709 USA

Email: msds@gsk.com

Website: www.gsk.com

EMERGENCY CONTACTS

VERISK 3E GLOBAL INCIDENT RESPONSE

Telephone: +(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response

Contract Number: 334878

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Not classified.

Environmental hazards Hazardous to the aquatic environment, acute hazard Category 3

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word None.

Hazard statement Harmful to aquatic life.

Precautionary statement

Prevention Avoid release to the environment.

Response Not available.

Storage Not available.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information

9.58% of the mixture consists of component(s) of unknown acute oral toxicity. 25.055% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 14.58% of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

3. Composition/information on ingredients**Mixtures**

Chemical name	Common name and synonyms	CAS number	%
PHARMACEUTICAL GRADE PETROLATUM	PETROLEUM JELLY VASELINE WHITE PETROLEUM JELLY WHITE PETROLEUM USP PETROLATO (PETROLIO) PETROLATUM PRETOLATO PÉTROLATUM VASELIN WHITE PETROLATUM USP YELLOW PETROLATUM SOFT PARAFFIN	8009-03-8	48
PHARMACEUTICAL GRADE PARAFFIN WAX	PARAFFIN HARD PARAFFIN PARAFFIN WAXES AND HYDROCARBON WAXES WHITE SOFT PARAFFIN	8002-74-2	21.3
LIQUID PARAFFIN	LIQUID PARAFFIN, BP LIGHT LIQUID PARAFFIN HIGHLY-REFINED MINERAL OIL WHITE LIQUID PARAFFIN LIQUID PETROLATUM PARAFFIN OILS MINERAL SOLVENT (VARSOL) OIL, MINERAL PETROLATUM, LIQUID LIQUID PARAFFIN	8012-95-1	10.475
2-OCTYL-1-DODECANOL	1-DODECANOL, 2-OCTYL-2-OCTYLDODECAN-1-OL 2-OCTYLDODECANOL 2-OCTYLDODECYL ALCOHOL OCTYL DODECANOL OCTYLDODECANOL 2-OCTYLDODECANOL-1	5333-42-6	5
BENZYL BENZOATE	ASCABIN ASCABIOL BENYLATE BENZOIC ACID, BENZYL ESTER BENZYL ALCOHOL BENZOIC ESTER BENZYL BENZENECARBOXYLATE BENZYL PHENYLFORMATE	120-51-4	2.11
BEESWAX	YELLOW BEESWAX WHITE BEESWAX BEESWAX (WHITE) BEESWAX ABSOLUTE BEESWAX BLEACHED (WHITE), SYNTHETIC 619 BEESWAX OIL, ABSOLUTE BEESWAX YELLOW OHS02556	8012-89-3	2
ISOPROPYL MYRISTATE	TETRADECANOIC ACID, ISOPROPYL ESTER MYRISTIC ACID, ISOPROPYL ESTER ISOPROPYL TETRADECANOATE	110-27-0	1
Flavors	NOT ASSIGNED		0.52

Chemical name	Common name and synonyms	CAS number	%
CETYL ALCOHOL	1-HEXADECANOL HEXADECYL ALCOHOL N-1-HEXADECANOL N-CETYL ALCOHOL 1-HEXADECYL ALCOHOL CETEARYL ALCOHOL PALMITYL ALCOHOL	36653-82-4	0.5
SACCHARIN	1,2-BENZISOTHIAZOL-3(2H)-ONE, 1,1-DIOXIDE ANHYDRO-O-SULFAMINEBENZOIC ACI D BENZOIC SULPHINIDE O-BENZOYL SULFIMIDE SACCHARIN INSOLUBLE	81-07-2	0.075
FD AND C BLUE NO. 1 ALUMINUM LAKE	BENZENEMETHANAMINIUM, N-ETHYL-N-(4-((4-(ETHYL((3-SULFOPHENYL) METHYL) AMINO) PHENYL)(2-SULFOPHENYL) METHYLENE)-2,5-CYCLOHEXADIEN-1-YLIDENE) -3-SULFOHYDROXIDE, INNER SALT, ALUMINUM SALT C.I. 42090:2 C.I. FOOD BLUE 2:1 C.I. FOOD BLUE 2 ALUMINUM LAKE FD AND C BLUE NO.1 LAKE	68921-42-6	0.0016

4. First-aid measures

Inhalation	No specific treatment is necessary since this material is not likely to be hazardous by inhalation.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth.
Most important symptoms/effects, acute and delayed	Health injuries are not known or expected under normal use.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.
General information	Get medical attention if any discomfort continues.

5. Fire-fighting measures

Suitable extinguishing media	Foam. Dry powder. Dry sand. Dry chemicals. Carbon dioxide (CO2).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Cool containers exposed to heat with water spray and remove container, if no risk is involved.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	Will burn if involved in a fire. No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Prevent product from entering drains. Stop the flow of material, if this is without risk. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage**Precautions for safe handling**

Observe good industrial hygiene practices.

**Conditions for safe storage,
including any incompatibilities**

None known.

8. Exposure controls/personal protection**Occupational exposure limits**

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

GSK

Components	Type	Value	Form
BEESWAX (CAS 8012-89-3)	OHC	1	
CETYL ALCOHOL (CAS 36653-82-4)	OHC	2	>5 - </=50 ppm
Flavors	OHC	3	>10 - <=100 mcg/m3 PROVISIONAL
SACCHARIN (CAS 81-07-2)	8 HR TWA	5000 mcg/m3	
	OHC	1	

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
LIQUID PARAFFIN (CAS 8012-95-1)	PEL	5 mg/m3	Mist.
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	PEL	5 mg/m3	Mist.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
FD AND C BLUE NO. 1 ALUMINUM LAKE (CAS 68921-42-6)	TWA	1 mg/m3	Respirable fraction.
LIQUID PARAFFIN (CAS 8012-95-1)	TWA	5 mg/m3	Inhalable fraction.
PHARMACEUTICAL GRADE PARAFFIN WAX (CAS 8002-74-2)	TWA	2 mg/m3	Fume.
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	TWA	5 mg/m3	Inhalable fraction.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
FD AND C BLUE NO. 1 ALUMINUM LAKE (CAS 68921-42-6)	TWA	2 mg/m3	
LIQUID PARAFFIN (CAS 8012-95-1)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.
PHARMACEUTICAL GRADE PARAFFIN WAX (CAS 8002-74-2)	TWA	2 mg/m3	Fume.
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	STEL	10 mg/m3	Mist.

US. NIOSH: Pocket Guide to Chemical Hazards
Components **Type**

Value **Form**

TWA

5 mg/m³

Mist.

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	General ventilation normally adequate.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
Skin protection	
Hand protection	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.
Other	No special protective equipment required. Wear suitable protective clothing as protection against splashing or contamination.
Respiratory protection	No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Thermal hazards	Not applicable.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance Waxy solid

Physical state Solid.

Form Not available.

Color Blue

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	No adverse effects due to inhalation are expected.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	Expected to be a low ingestion hazard.
Symptoms related to the physical, chemical and toxicological characteristics	Not available.

Information on toxicological effects

Acute toxicity	Based on available data, the classification criteria are not met.
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Components	Species	Test Results
BEESWAX (CAS 8012-89-3)		
Acute		
Oral		
LD50	Rat	> 5 g/kg
CETYL ALCOHOL (CAS 36653-82-4)		
Acute		
Oral		
LD50	Rat	5 g/kg
FD AND C BLUE NO. 1 ALUMINUM LAKE (CAS 68921-42-6)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
LIQUID PARAFFIN (CAS 8012-95-1)		
Acute		
Oral		
LD50	Mouse	22 g/kg
PHARMACEUTICAL GRADE PARAFFIN WAX (CAS 8002-74-2)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
		> 15 g/kg
Chronic		
Oral		
NOAEL	Rat	>= 3000 mg/kg, 2 years

Components	Species	Test Results
SACCHARIN (CAS 81-07-2)		
Acute		
Oral		
LD50	Mouse	17 g/kg
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Irritation Corrosion - Skin: P.I.I. value		
SACCHARIN	OECD 404, Data for sodium saccharin Result: Mild irritation Species: Rabbit	
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.	
Eye		
SACCHARIN	OECD 405, Data for sodium saccharin. Result: Moderate Irritant Species: Rabbit	
Respiratory or skin sensitization		
Respiratory sensitization	Based on available data, the classification criteria are not met.	
Skin sensitization	Based on available data, the classification criteria are not met.	
Germ cell mutagenicity	Based on available data, the classification criteria are not met.	
Carcinogenicity	Based on available data, the classification criteria are not met.	
PHARMACEUTICAL GRADE PETROLATUM	>= 3000 mg/kg/day 2 year bioassay, oral administration Result: NOAEL Species: Rat Dermal application Result: Negative Species: Mouse	
IARC Monographs. Overall Evaluation of Carcinogenicity		
SACCHARIN (CAS 81-07-2)	3 Not classifiable as to carcinogenicity to humans.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)		
Not listed.		
US. National Toxicology Program (NTP) Report on Carcinogens		
LIQUID PARAFFIN (CAS 8012-95-1)	Known To Be Human Carcinogen.	
Reproductive toxicity	Based on available data, the classification criteria are not met.	
Specific target organ toxicity - single exposure	Based on available data, the classification criteria are not met.	
Specific target organ toxicity - repeated exposure	Based on available data, the classification criteria are not met.	
Aspiration hazard	Based on available data, the classification criteria are not met.	

12. Ecological information

Ecotoxicity	Harmful to aquatic life. There is insufficient information to determine the scope of the environmental effects this material may cause.	
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Components	Species	Test Results
CETYL ALCOHOL (CAS 36653-82-4)		
Aquatic		
Acute		
Algae	EC50	Green algae (Scenedesmus subspicatus) 676 mg/l, 96 hours
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus) > 1000 mg/l, 96 hours
		Fathead minnow (Adult Pimephales promelas) > 500 mg/l, 5 days

Components	Species	Test Results
SACCHARIN (CAS 81-07-2)		
Aquatic		
Acute		
Fish	EC50	Fathead minnow (Adult Pimephales promelas)
		15000 mg/l, 96 hours
Persistence and degradability	No data is available on the degradability of this product.	
Photolysis		
Half-life (Photolysis-atmospheric)		
CETYL ALCOHOL		16.7 Hours Estimated
SACCHARIN		3 Days Estimated
Biodegradability		
Percent degradation (Aerobic biodegradation-inherent)		
CETYL ALCOHOL		0.4 %, < 1 day Other degradation test system, Activated sludge
		30 - 60 %, 5 days BOD5
Percent degradation (Aerobic biodegradation-ready)		
PHARMACEUTICAL GRADE PARAFFIN WAX		< 50 %
Bioaccumulative potential	Not available.	
Partition coefficient n-octanol / water (log Kow)		
BENZYL BENZOATE		3.97
SACCHARIN		0.91
Bioconcentration factor (BCF)		
CETYL ALCOHOL		> 9999 Measured
SACCHARIN		3 Estimated
Mobility in soil	No data available.	
Adsorption		
Soil/sediment sorption - log Koc		
CETYL ALCOHOL		3.58 - 4.67 Estimated
SACCHARIN		1.88 Estimated
Mobility in general		
Volatility		
Henry's law		
CETYL ALCOHOL		0.000073 atm m^3/mol Estimated
SACCHARIN		0 atm m^3/mol Estimated
Other adverse effects	None known.	
13. Disposal considerations		
Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.	
Local disposal regulations	Dispose in accordance with all applicable regulations.	
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.	
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).	
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.	

14. Transport information

DOT	Not regulated as a dangerous good.
	Read safety instructions, SDS and emergency procedures before handling.
IATA	Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

US state regulations

California Proposition 65

For more information go to www.P65Warnings.ca.gov.

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

LIQUID PARAFFIN (CAS 8012-95-1)

PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*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).

16. Other information, including date of preparation or last revision

Issue date	04-08-2017
Revision date	03-27-2021
Version #	02
HMIS® ratings	Health: 0 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 0 Flammability: 0 Instability: 0
References	GSK Hazard Determination
Disclaimer	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.
Revision information	This document has undergone significant changes and should be reviewed in its entirety.