

MATERIAL SAFETY DATA SHEET

Version: 3
Revision Date: June 22, 2009**EXCEDRIN®****1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING**

Product Name/Identifier	: Excedrin® Extra Strength Excedrin® Migraine Excedrin® ES (<i>synonym</i>) Excedrin® ES/Migraine (<i>synonym</i>)
Material Number	: 2001146 (caplets) 2001147 (tablets)
Manufacturer's Name/Address in U.S.	: Novartis Consumer Health, Inc. 200 Kimball Drive Parsippany, NJ 07054 USA
Supplier's Name/Address in U.S.	: Novartis Consumer Health, Inc. 200 Kimball Drive Parsippany, NJ 07054 USA
Information Telephone Number	: (800) 452-0051 (24 hours / 7 days a week) Novartis Consumer and Professional Affairs Call Center
ChemTel Emergency Telephone Number	: (800) 255-3924 (24 hours / 7 days a week) [International: +01-813-248-0585 (collect)]
Preparer Information	: Health, Safety & Environmental Dept. Novartis Consumer Health, Inc. Telephone: (402) 464-6311

2. COMPOSITION/INFORMATION ON INGREDIENTS**Product Information**

Product Use	: This product is a non-prescription drug intended to provide temporary relief from pain associated with migraine headaches.
Active Ingredients	: · Acetaminophen · Aspirin · Caffeine

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Composition Information

<u>Component¹</u>	<u>CAS Registry Number</u>	<u>Concentration</u>	<u>Exposure Limits</u>
Acetaminophen	103-90-2	Trade secret	Not established
Aspirin	50-78-2	Trade secret	5 mg/m ³ (ACGIH-TWA)
Cellulose microcrystalline	9004-34-6	Trade secret	See Note-2
Caffeine	58-08-2	Trade secret	Not established

Notes on Composition Information

¹ Hazardous/non-hazardous components present at or greater than 1% (0.1%).

² OSHA has an established standard for particulates not otherwise regulated (nuisance dust) set at 5 mg/m³ (respirable fraction) and 15 mg/m³ (total dust). ACGIH has established an exposure value of 3 mg/m³ (respirable fraction) and 10 mg/m³ (inhalable fraction) for particulates not otherwise classified.

3. HAZARDS IDENTIFICATION

Emergency Overview

White film-coated caplets or tablets. Not expected to present a health, flammability, or reactivity hazard. Avoid release to the environment.

Hazard Rating System (HMIS)

Health = 1

Flammability = 1

Physical Hazard = 0

Potential Health Effects

- | | | |
|---|---|--|
| Eyes | : | This product is not expected to cause eye irritation. |
| Skin Irritation/Sensitization/Absorption | : | This product is not expected to be irritating to the skin, cause skin sensitization, or be absorbed through the skin. |
| Ingestion | : | Ingestion is generally not expected to occur or present a hazard during normal conditions of use. Over ingestion of this product may result in adverse effects. |
| Inhalation | : | This product is generally not expected to be harmful by inhalation. |
| Subchronic Toxicity | : | There are no subchronic toxicity data on this product. Based on the data of the individual components, the subchronic toxicity of this product is expected to be moderately low. |
| Reproductive Toxicity | : | There are no reproductive toxicity data on this product. Based on the data of the individual components, this product is not expected to present a reproductive toxicity hazard. |

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Teratogenicity (birth defects)	:	There are no teratogenicity data on this product. Aspirin, an active ingredient in this product, has been shown to be a developmental toxicant. The U.S. Food and Drug Administration has issued the following warning about aspirin use during pregnancy: <i>It is especially important not to use aspirin during the last three months of pregnancy unless specifically directed to do so by a physician because it may cause problems in the unborn child or complications during delivery.</i> If you are pregnant or nursing a baby, seek the advice of a health care professional before using this product.
Mutagenicity	:	There are no mutagenicity data on this product. Based on the data of the individual components, this product is not expected to present a mutagenicity hazard.
Chronic Effects/Carcinogenicity	:	There are no chronic effects or carcinogenicity data on this product. Based on the data of the individual components, this product is generally not expected to present a chronic or carcinogenicity hazard. · NTP: Not listed · IARC: Not listed · OSHA: Not listed
Medical Conditions Aggravated by Exposure	:	Children and teenagers should not use this product for chicken pox or flu symptoms unless a health care professional is consulted about Reye's Syndrome. Excessive exposure may have adverse effects on liver or kidney functions.
Incompatibility	:	A health care professional should be consulted before taking this product if an individual is already taking a prescription drug for anticoagulation, diabetes, gout, or arthritis. This product should not be taken with tetracycline antibiotics.
Signs & Symptoms of Exposure	:	Excessive exposure may cause gastrointestinal effects (including stomach bleeding), ringing in the ears, central nervous system (CNS) effects, liver effects, nausea, or excitability/nervousness.

4. FIRST AID MEASURES

Skin Contact	:	Wash skin with soap and water. If irritation develops, seek medical attention.
Eye Contact	:	Flush eyes with water for several minutes. If irritation develops, seek medical attention.

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- Inhalation** : If small amounts of this product are inhaled, specific treatment is generally not expected to be necessary. If exposed to excessive levels, if contact is prolonged, or if exposure causes adverse symptoms, move person to fresh air and get immediate medical attention.
- Ingestion** : In case of accidental overdose/over-ingestion, seek medical attention or contact a poison control center immediately.
- Note to Physicians** : This product is a non-prescription drug intended to provide temporary relief from pain associated with migraine headaches. This product contains the active ingredients acetaminophen, aspirin, and caffeine. See Section 2 for the individual components in this product.
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5. FIRE FIGHTING MEASURES

- Flash Point** : Not applicable.
- Flammable Limits** : Not available.
- Autoignition Temperature** : Not available.
- Hazardous Combustion Products** : Thermal decomposition may generate toxic vapors.
- Extinguishing Media** : Use water spray, carbon dioxide, dry chemical, or alcohol foam when fighting fires involving this material.
- Fire Fighting Instructions** : This material is not flammable, however, it will burn. Wear a self-contained breathing apparatus pressure demand (MSHA/NIOSH approved or equivalent) and full protective gear.
- Explosion Data** : Not available.
- Other** : None.
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6. ACCIDENTAL RELEASE MEASURES

- Spill and Cleanup Procedures** : Sweep up spilled material and place in a disposal container. This product may be slippery if spilled.
- Other Instructions** : Do not reuse recovered material. Avoid release of this product to the environment.
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Handling	:	Avoid contact with skin and eyes. Handle only in well ventilated locations.
Storage	:	Store in a cool dry area. Do not expose to heat, flames, or ignition sources. Keep away from food and drinking water.

8. EXPOSURE CONTROL AND PERSONAL PROTECTION

Eye/Face Protection	:	Eye protection should be worn during use and handling operations. Face protection should be worn when there is a potential for exposure to the face.
Skin Protection	:	Skin protection including gloves, protective clothing, and chemical-resistant footwear should be worn when there is a potential for dermal exposure to this product during use and handling operations.
Respiratory Protection	:	Respiratory protection is not expected to be necessary during use and handling operations unless the product (or its dust) becomes airborne above low levels.
Engineering Controls	:	Good general ventilation should be sufficient to control low airborne levels of the product. If the product is present above low levels, local exhaust or other measures may be necessary to control worker exposure.
Exposure Guidelines	:	There are no established exposure guidelines or limits for this product. <u>See</u> Section 2 for additional information.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance/Physical State	:	White film-coated caplets or tablets
Odor	:	No odor
pH	:	Not available
Vapor Pressure	:	Not available
Vapor Density	:	Not available
Boiling Point	:	Not available
Freezing/Melting Point	:	Not available
Specific Gravity	:	Not available
Octanol/Water Partition Coefficient	:	Not available
Solubility in Water	:	Soluble
Volatility	:	Not available

10. STABILITY AND REACTIVITY

Stability	:	Stable under normal use and storage conditions.
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Conditions to Avoid	:	None.
Incompatibility/Materials to Avoid	:	None.
Hazardous Decomposition or Byproducts	:	None.
Hazardous Polymerization	:	Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Toxicological Data	:	There are no acute toxicological data on this product. Based on the data of the individual components, including the active ingredients, the acute toxicity of this product is expected to be moderately low.
Eye Irritation Data	:	This product is not expected to cause eye irritation.
Skin Irritation/Sensitization/Absorption Data	:	This product is not expected to be irritating to the skin, cause skin sensitization, or be absorbed through the skin.
Subchronic Toxicity Data	:	There are no subchronic toxicity data on this product. Based on the data of the individual components, including the active ingredients, the subchronic toxicity of this product is expected to be moderately low.
Reproductive Toxicity Data	:	There are no reproductive toxicity data on this product. Based on the data of the individual components, including the active ingredients, this product is not expected to present a reproductive toxicity hazard.
Teratogenicity (birth defects) Data	:	There are no teratogenicity data on this product. Aspirin, an active ingredient in this product, has been shown to be a developmental toxicant. The U.S. Food and Drug Administration has issued the following warning about aspirin use during pregnancy: <i>It is especially important not to use aspirin during the last three months of pregnancy unless specifically directed to do so by a physician because it may cause problems in the unborn child or complications during delivery.</i> If you are pregnant or nursing a baby, seek the advice of a health care professional before using this product.
Mutagenicity Data	:	There are no mutagenicity data on this product. Based on the data of the individual components, including the active ingredients, this product is not expected to present a mutagenicity hazard. <u>Acetaminophen</u> has produced mixed results in <i>in vitro</i> mutagenicity assays. In <i>in vivo</i> mutagenicity assays, acetaminophen has generally yielded positive results. <u>Aspirin</u> has produced mixed results in <i>in vitro</i> mutagenicity assays. Limited <i>in vivo</i> mutagenicity testing of aspirin has produced negative results. <u>Caffeine</u> has produced mixed results in <i>in vitro</i> and <i>in vivo</i> mutagenicity testing.

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Chronic/Carcinogenicity Data : There are no chronic effects or carcinogenicity data on this product. Based on the data of the individual components, including the active ingredients, this product is generally not expected to present a chronic or carcinogenicity hazard. Acetaminophen was tested in rats and mice in NTP carcinogenicity assays. Under the conditions of these 2-year studies, there was no evidence of carcinogenicity of acetaminophen for male rats or male or female mice; there was equivocal evidence of carcinogenicity in female rats. Aspirin has been evaluated in several carcinogenicity assays in which the results generally showed no evidence or carcinogenicity. Caffeine is identified as an IARC Group 3 agent: *Not classifiable as to its carcinogenicity to humans*.

12. ECOLOGICAL INFORMATION

Ecotoxicological Data : No ecotoxicological data are available on this product. Based on the data of the individual components, this product is generally not expected to cause adverse effects in the environment.

Environmental Fate Data : No environmental fate data are available on this product. Based on the data of the individual components, this product is generally expected to be biodegradable and not expected to bioaccumulate.

Physical/Chemical Properties : No physical/chemical properties data are available on this product.

13. DISPOSAL CONSIDERATIONS

Waste Classification : If discarded in its manufactured form, this product is a solid waste under RCRA. It is the responsibility of the user to determine at the time of disposal whether a material containing the product or derived from the product should be classified as a solid or hazardous waste.

U.S. EPA Waste Number : Not applicable.

Special Instructions : Avoid release of this product to the environment. Dispose as a solid waste in conformance with all federal, state, and local regulations.

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14. TRANSPORT INFORMATION

U.S. DOT

UN Number	:	-
Hazard Class	:	-
Packing Group	:	-
Proper Shipping Name	:	-
Label	:	-
Marine Pollutant	:	-
Additional Information/Remarks	:	Not regulated as a hazardous material/dangerous goods.

IMDG

UN Number	:	-
Hazard Class	:	-
Packing Group	:	-
Proper Shipping Name	:	-
Label	:	-
Marine Pollutant	:	-
Additional Information/Remarks	:	Not regulated as a hazardous material/dangerous goods.

ICAO/IATA

UN Number	:	-
Hazard Class	:	-
Packing Group	:	-
Proper Shipping Name	:	-
Label	:	-
Marine Pollutant	:	-
Additional Information/Remarks	:	Not regulated as a hazardous material/dangerous goods.

15. REGULATORY INFORMATION

OSHA	:	This product may be considered hazardous under the OSHA Hazard Communication Standard.
U.S. FDA	:	This product is regulated under the U.S. Federal Food, Drug, and Cosmetics Act.
Waste Classification	:	If discarded in its manufactured form, this product is a solid waste under RCRA. However, it is the responsibility of the user to determine at the time of disposal whether a material containing the product or derived from the product should be classified as a solid or hazardous waste. See Section 13 for additional information.
EPCRA/SARA III	:	This product contains no toxic chemicals at or above the <i>de-minimis</i> threshold subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR 372.

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- International Regulations** : This product may be regulated by various countries' drug-regulating agencies.
- California Proposition 65** : This product is in compliance with California Proposition 65.
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16. OTHER INFORMATION

- Label Text** : See product packaging and the *Physician's Desk Reference for Non-Prescription Drugs*.
- Disclaimer** : The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information, and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal, and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.
- Previous MSDS Version Date** : October 6, 2006
April 8, 2009
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