1. Identification

Product identifier: CONRAY®

CAS #: Mixture

Other means of identification:
- SDS number: CONRY
- Synonyms: Conray® 30, Conray® 43, Conray® 60 (280), Cysto Conray® II, Iothalamate Meglumine

Recommended use: Diagnostic imaging agent.

Recommended restrictions: None known.

Manufacturer/Importer/Supplier/Distributor information:
- Manufacturer: Mallinckrodt
- Address: 675 McDonnell Blvd., Hazelwood, MO 63042
- Telephone: Not available.
- Emergency phone number:
  - Customer Service: 888-744-1414
  - 24 Hour Emergency: 314-654-1600
  - Chemtrec: 800-424-9300
- E-mail: Not available.

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards:
- Sensitization, respiratory: Category 1
- Sensitization, skin: Category 1

Environmental hazards: Not classified.

OSHA defined hazards: Not classified.

Labeling:
- Contains: IOTHALAMATE MEGLUMINE, WATER

Label elements:
- Signal word: Danger
- Hazard statement: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
- Precautionary statement:
  - Prevention: Avoid breathing mist or vapor. In case of inadequate ventilation wear respiratory protection. Wear protective gloves. Contaminated work clothing must not be allowed out of the workplace.
  - Response: If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor. Wash contaminated clothing before reuse.
  - Storage: Store away from incompatible materials.
  - Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)  
None known.

Supplemental information
Read Package Insert prior to use. Ensure prompt removal from skin, eyes and clothing. As part of good laboratory and personal hygiene and safety procedure, avoid all unnecessary exposure to the chemical substance.

As with all contrast media, containers should be inspected prior to use to ensure that breakage or other damage has not occurred during shipping and handling. All containers should be inspected for closure integrity. Damaged containers should not

As per 29 CFR 1910.1200(b)(5)(iii), any food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, including materials intended for use as ingredients in such products (e.g. flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and regulations issued under that Act, when they are subject to the labeling requirements under that Act by the Food and Drug Administration are exempted from the requirements of the Hazard Communication Standard.

All Mallinckrodt finished products are labeled in compliance with the requirements of the Food and Drug Administration (FDA) and must be used in the prescribed manner. Each package of the finished pharmaceutical product is supplied with a package insert (approved labeling) which provides necessary drug safety information.

3. Composition/information on ingredients

Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>WATER</td>
<td></td>
<td>7732-18-5</td>
<td>40-70</td>
</tr>
<tr>
<td>IOTHALAMATE MEGLUMINE</td>
<td></td>
<td>13087-53-1</td>
<td>30-60</td>
</tr>
</tbody>
</table>

Composition comments
All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

Inhalation
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Call a physician if symptoms develop or persist.

Skin contact
Wash off with soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

Eye contact
Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

Ingestion
If ingestion of a large amount does occur, call a poison control center immediately. Rinse mouth. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
May cause allergic respiratory and skin reactions.

The following adverse reactions have been observed in conjunction with the use of iodine-containing contrast agents.

The most frequent adverse reactions are nausea, vomiting, facial flush and a feeling of body warmth. These are usually of brief duration. Other reactions include the following:

Hypersensitivity reactions: Dermal manifestations of urticaria with or without pruritus, erythema and maculopapular rash. Dry mouth. Sweating. Conjunctival symptoms. Facial, peripheral and angioneurotic edema. Symptoms related to the respiratory system include sneezing, nasal stuffiness, coughing, choking, dyspnea, chest tightness and wheezing, which may be initial manifestations of more severe and infrequent reactions including asthmatic attack, laryngospasm and bronchospasm with or without edema, pulmonary edema, apnea and cyanosis. Rarely, these allergic-type reactions can progress into anaphylaxis with loss of consciousness and coma and severe cardiovascular disturbances.

Cardiovascular reactions: Generalized vasodilation, flushing and venospasm. Occasionally, thrombosis or rarely, thrombophlebitis. Red blood cell clumping and agglutination, crenation and interference in clot formation. Extremely rare cases of disseminated intravascular coagulation resulting in death have been reported. Severe cardiovascular responses include rare cases of hypotensive shock, coronary insufficiency, cardiac arrhythmia, fibrillation and arrest. These severe reactions are usually reversible with prompt and appropriate management; however, fatalities have occurred.

Endocrine reactions: Thyroid function tests indicative of hypothyroidism or transient thyroid suppression have been uncommonly reported following iodinated contrast media administration to adult and pediatric patients, including infants. Some patients were treated for hypothyroidism.

Technique reactions: Extravasation with burning pain, hematomas, ecchymosis and tissue necrosis, paresthesia or numbness, vascular constriction due to injection rate, thrombosis and thrombophlebitis.

Neurological reactions: Spasm, convulsions, aphasia, syncope, paresis, paralysis resulting from spinal cord injury and pathology associated with syndrome of transverse myelitis, visual field losses which are usually transient but may be permanent, coma and death.

Other reactions: Headache, trembling, shaking, chills without fever and lightheadedness. Temporary renal shutdown or other nephropathy.

Serious adverse reactions have been reported due to the inadvertent intrathecal administration of iodinated contrast media that are not indicated for intrathecal use. These serious adverse reactions include: death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema. Special attention must be given to ensure that this drug product is not administered intrathecally.

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before reuse.
Special protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

Fire-fighting equipment/ instructions

In the event of fire, cool tanks with water spray. Move containers from fire area if you can do so without risk.

Specific methods

Cool containers exposed to flames with water until well after the fire is out.

General fire hazards

No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

No special precautions are necessary beyond normal good hygiene practices. See Section 8 of the SDS for additional personal protection advice when handling this product.

Methods and materials for containment and cleaning up

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece).

Large Spills: Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Following product recovery, flush area with water. Clean surface thoroughly to remove residual contamination.

Environmental precautions

For waste disposal, see section 13 of the SDS.

7. Handling and storage

Precautions for safe handling

Avoid contact with skin, eyes and clothing. Protect from light. Protect from freezing. Handle and open container with care. Do not handle until all safety precautions have been read and understood. Avoid breathing mist or vapor. Do not ingest. When using, do not eat, drink or smoke. Wear personal protective equipment. Wash thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Keep container tightly closed. Store in a cool place below 86 °F (30 °C). Protect from freezing and direct sunlight. Store away from incompatible materials (see Section 10 of the SDS). Use care in handling/storage. Store in accordance with local/regional/national/international regulation.

8. Exposure controls/personal protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

No exposure standards allocated.

Appropriate engineering controls

General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses. Provide eyewash station and safety shower.

Skin protection

Hand protection

Wear protective gloves.

Other

Wear appropriate chemical resistant clothing.

Respiratory protection

In case of insufficient ventilation wear suitable respiratory equipment.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance

Clear.

Physical state

Liquid.

Form

Liquid.

Color

Colorless.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

32 °F (0 °C) estimated
### 1. Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
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<td>212 °F (100 °C) estimated</td>
</tr>
<tr>
<td>range</td>
<td></td>
</tr>
<tr>
<td>Flash point</td>
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</tr>
<tr>
<td>Evaporation rate</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive</td>
<td></td>
</tr>
<tr>
<td>limits</td>
<td></td>
</tr>
<tr>
<td>Flammability limit - lower (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flammability limit - upper (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Explosive limit - lower (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Explosive limit - upper (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>0.00001 hPa estimated</td>
</tr>
<tr>
<td>Vapor density</td>
<td>Not available.</td>
</tr>
<tr>
<td>Relative density</td>
<td>1 - 1.5</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Solubility (water)</td>
<td>Complete</td>
</tr>
<tr>
<td>Partition coefficient</td>
<td>Not available.</td>
</tr>
<tr>
<td>(n-octanol/water)</td>
<td></td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>Not available.</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not available.</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

### 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. Freezing. Heat. Light.
- **Incompatible materials**: Strong oxidizing agents.
- **Hazardous decomposition products**: Toxic gas. Nitrogen oxides (NOx). Iodine.

### 11. Toxicological Information

#### Information on likely routes of exposure

- **Ingestion**: Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.
- **Inhalation**: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- **Skin contact**: May cause skin irritation. May cause an allergic skin reaction.
- **Eye contact**: Contact with eyes may cause irritation.
Symptoms related to the physical, chemical and toxicological characteristics

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Other reactions: Headache, trembling, shaking, chills without fever and lightheadedness. Temporary renal shutdown or other nephropathy.

Information on toxicological effects

Acute toxicity
Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Chronic effects
None known through occupational exposure.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONRAY® (CAS Mixture)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td>Rat</td>
<td>205 mg/kg Intracerebral</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>10.5 g/kg Intravenous</td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>May cause skin irritation.</td>
<td></td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Contact with eyes may cause irritation.</td>
<td></td>
</tr>
<tr>
<td>Respiratory or skin sensitization</td>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled.</td>
<td></td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>May cause an allergic skin reaction.</td>
<td></td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.</td>
<td></td>
</tr>
</tbody>
</table>

Material name: CONRAY®
MSDS ID: CONRY Version #: 01 Revision date: 09-11-2015
Carcinogenicity
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Reproductive toxicity
Reproduction studies have been performed in mice, rats, and rabbits at doses up to 6.6 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Conray. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Iothalamate salts are excreted unchanged in human milk. Because of the potential for adverse effects in nursing infants, bottle feedings should be substituted for breast feedings for 24 hours following the administration of this drug.

Specific target organ toxicity - single exposure
Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure
Due to lack of data the classification is not possible.

Aspiration hazard
Due to lack of data the classification is not possible.

Further information
Fatalities have been reported following the administration of iodine-containing contrast agents. Based upon clinical literature.

12. Ecological information
Ecotoxicity
The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Because this product is intended for use by hospital or clinic patients, it is expected to be treated by standard wastewater treatment facilities with no adverse environmental impacts.

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulative potential
No data available.

Mobility in soil
No data available.

Other adverse effects
None known.

13. Disposal considerations
Disposal instructions
Dispose of contents/container in accordance with local/regional/national/international regulations. If medical waste is involved, such as blood, blood products, or sharps, the waste must be handled as a biohazard and disposed of accordingly. If not a biohazard, consult local, state and federal regulations for proper disposal.

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
Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information
DOT
Not regulated as dangerous goods.

IATA
Not regulated as dangerous goods.

IMDG
Not regulated as dangerous goods.
This substance/mixture is not intended to be transported in bulk.

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

15. Regulatory information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. TSCA exempt status.

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 1910.1001-1050)
Not listed.

CERCLA (Superfund) reportable quantity
None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical
Yes

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)
Not regulated.

US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

US. Massachusetts RTK - Substance List
Not regulated.

US. New Jersey Worker and Community Right-to-Know Act
Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law
Not listed.

US. Rhode Island RTK
Not regulated.

US. California Proposition 65
Not Listed.

International Inventories

Country(s) or region | Inventory name | On inventory (yes/no)*
--- | --- | ---
Australia | Australian Inventory of Chemical Substances (AICS) | No
Canada | Domestic Substances List (DSL) | Yes
<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
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<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Issue date</th>
<th>09-11-2015</th>
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<tbody>
<tr>
<td>Version #</td>
<td>01</td>
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Revision Information

Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties
Regulatory Information: Risk Phrases - Class.
HazReg Data: North America
GHS: Classification