

| Version | Revision Date: | SDS Number: | Date of last issue: 2020/10/10 |
|---------|----------------|---------------|---------------------------------|
| 4.3 | 2021/04/09 | 1832968-00012 | Date of first issue: 2017/07/13 |

1. PRODUCT AND COMPANY IDENTIFICATION

| Product name | : | Betamethasone / Salicylic Acid Lotion Formulation | | | | |
|---|----------|--|--|--|--|--|
| Manufacturer or supplier's de Company | eta : | ils Organon & Co. | | | | |
| Address | : | 30 Hudson Street, 33nd floor Jersey City, New Jersey, U.S.A 07302 | | | | |
| Telephone | : | 551-430-6000 | | | | |
| Emergency telephone number | : | 215-631-6999 | | | | |
| E-mail address | : | EHSSTEWARD@organon.com | | | | |
| Recommended use of the chemical and restrictions on use | | | | | | |

| Recommended use | : | Pharmaceutical |
|-----------------|---|----------------|
| | | |

2. HAZARDS IDENTIFICATION

Emergency Overview

| Appearance | : lotion | | | |
|--|---------------------------|--|--|--|
| Colour | : colourless, translucent | | | |
| Odour | : No data available | | | |
| Highly flammable liquid and vapour. Causes skin irritation. Causes serious eye irritation. May cause drowsiness or dizziness. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects. | | | | |

GHS Classification

| Flammable liquids | : | Category 2 |
|--|---|-------------|
| Skin corrosion/irritation | : | Category 2 |
| Serious eye damage/eye irri- tation | : | Category 2A |
| Reproductive toxicity | : | Category 1B |
| Specific target organ toxicity - single exposure | : | Category 3 |
| Specific target organ toxicity - repeated exposure | : | Category 1 |
| Long-term (chronic) aquatic hazard | : | Category 1 |

according to GB/T 16483 and GB/T 17519



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| GHS label elem | ents | | |
| Hazard pictogram | ms | | |
| Signal word | | : Danger | |
| Hazard statemen | nts | H315 Causes sk H319 Causes se H336 May cause H360D May dam H372 Causes da exposure. | nmable liquid and vapour. in irritation. rious eye irritation. e drowsiness or dizziness. hage the unborn child. Image to organs through prolonged or repeated to aquatic life with long lasting effects. |
| Precautionary st | atements | P202 Do not har and understood. P210 Keep away No smoking. P233 Keep conta P241 Use explos ment. P242 Use only n P243 Take preca P260 Do not bre P264 Wash skin P270 Do not eat P271 Use only o P273 Avoid relea | cial instructions before use. adle until all safety precautions have been read of from heat/ sparks/ open flames/ hot surfaces. ainer tightly closed. sion-proof electrical/ ventilating/ lighting equip- on-sparking tools. autionary measures against static discharge. athe mist or vapours. thoroughly after handling. , drink or smoke when using this product. utdoors or in a well-ventilated area. ase to the environment. ective gloves/ protective clothing/ eye protec- ion. |
| | | ly all contaminate P304 + P340 + F and keep comfor doctor if you feel P305 + P351 + F for several minut easy to do. Cont P308 + P313 IF attention. P332 + P313 If s tion. P337 + P313 If e tention. | 2338 IF IN EYES: Rinse cautiously with water es. Remove contact lenses, if present and |

according to GB/T 16483 and GB/T 17519



Betamethasone / Salicylic Acid Lotion Formulation

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P391 Collect spillage.

Storage:

P403 + P235 Store in a well-ventilated place. Keep cool. P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Physical and chemical hazards

Highly flammable liquid and vapour.

Health hazards

Causes skin irritation. Causes serious eye irritation. May damage the unborn child. May cause drowsiness or dizziness. Causes damage to organs through prolonged or repeated exposure.

Environmental hazards

Very toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification

Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|------------------|-----------|-----------------------|
| Propan-2-ol | 67-63-0 | >= 30 -< 50 |
| salicylic acid | 69-72-7 | >= 1 -< 3 |
| Sodium hydroxide | 1310-73-2 | >= 0.5 -< 1 |
| betamethasone | 378-44-9 | >= 0.025 -< 0.1 |

4. FIRST AID MEASURES

| General advice | : | In the case of accident or if you feel unwell, seek medical ad- vice immediately. When symptoms persist or in all cases of doubt seek medical advice. |
|-------------------------|---|--|
| If inhaled | : | If inhaled, remove to fresh air. Get medical attention. |
| In case of skin contact | : | In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. |
| In case of eye contact | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. |



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| If swallowed Most important symptoms and effects, both acute and delayed | | : | Get medical attention. If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. Causes skin irritation. Causes serious eye irritation. May cause drowsiness or dizziness. May damage the unborn child. Causes damage to organs through prolonged or repeated | | |
| Protection of first-aiders | | : | Causes damage to organs through prolonged or repeated exposure. First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). | | |
| 1 | Notes to | o physician | : | | cally and supportively. |
| 5. FIF | REFIGH | ITING MEASURES | | | |
| Suitable extinguishing media | | : | Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical | | |
| | Unsuitable extinguishing media Specific hazards during fire- fighting | | : | High volume wate | r jet |
| | | | : | fire. Flash back possib Vapours may form | water stream as it may scatter and spread le over considerable distance. n explosive mixtures with air. pustion products may be a hazard to health. |
| | Hazardo ucts | ous combustion prod- | : | Carbon oxides | |
| | Specific ods | c extinguishing meth- | : | cumstances and t Use water spray to | measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do |
| | Special for firefi | protective equipment ghters | : | | , wear self-contained breathing apparatus. ective equipment. |

6. ACCIDENTAL RELEASE MEASURES

| Personal precautions, protec- tive equipment and emer- gency procedures | : | Remove all sources of ignition. Ventilate the area. Use personal protective equipment. Follow safe handling advice (see section 7) and personal pro- tective equipment recommendations (see section 8). |
|---|---|---|
| Environmental precautions | : | Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). |



| Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained. Methods and materials for containment and cleaning up Non-sparking tools should be used. Soak up with inert absorbent material. Suppress (knock down) gases/vapours/mists with a water spray jet. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor- | Version 4.3 | Revision Date: 2021/04/09 | SDS Number: 1832968-00012 | Date of last issue: 2020/10/10 Date of first issue: 2017/07/13 |
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| bent. Local or national regulations may apply to releases and dis- posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter- mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. | | | Local authorities cannot be contained Non-sparking toor Soak up with ine Suppress (knock spray jet. For large spills, present to keep mather be pumped, stor Clean up remained bent. Local or national posal of this mather employed in the mine which regunations of the start | should be advised if significant spillages ned. ols should be used. rt absorbent material. a down) gases/vapours/mists with a water provide dyking or other appropriate contain- terial from spreading. If dyked material can e recovered material in appropriate container. ing materials from spill with suitable absor- regulations may apply to releases and dis- erial, as well as those materials and items cleanup of releases. You will need to deter- lations are applicable. 15 of this SDS provide information regarding |

7. HANDLING AND STORAGE

| Handling | | |
|-----------------------------|---|--|
| Technical measures | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation. Use explosion-proof electrical, ventilating and lighting equip- ment. |
| Advice on safe handling | : | Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- sessment Non-sparking tools should be used. Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment. |
| Avoidance of contact | : | Oxidizing agents |
| Storage | | |
| Conditions for safe storage | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. |



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| Mate | rials to avoid | Store in accorda Keep away from Do not store wit Self-reactive su Organic peroxid Oxidizing agent Flammable gas Pyrophoric liqui Pyrophoric solic | s es ds ls ostances and mixtures |
| Pack | aging material | : Unsuitable mate | erial: None known. |

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

| Components | CAS-No. | Value type (Form of exposure) | Control parame- ters / Permissible concentration | Basis |
|------------------|----------------|-------------------------------------|--|----------|
| Propan-2-ol | 67-63-0 | PC-TWA | 350 mg/m3 | CN OEL |
| | | PC-STEL | 700 mg/m3 | CN OEL |
| | | TWA | 200 ppm | ACGIH |
| | | STEL | 400 ppm | ACGIH |
| salicylic acid | 69-72-7 | TWA | 100 µg/m3 (OEB 2) | Internal |
| | Further inform | nation: DSEN | | |
| | | Wipe limit | 100 µg/100 cm2 | Internal |
| Sodium hydroxide | 1310-73-2 | MAC | 2 mg/m3 | CN OEL |
| | | С | 2 mg/m3 | ACGIH |
| betamethasone | 378-44-9 | TWA | 1 µg/m3 (OEB 4) | Internal |
| | Further inform | nation: Skin | | |
| | | Wipe limit | 10 µg/100 cm ² | Internal |

Components with workplace control parameters

Biological occupational exposure limits

| Components | CAS-No. | Control parameters | Biological specimen | Sam- pling | Permissible concentra- | Basis |
|-------------|---------|--------------------|---------------------|---|------------------------|--------------|
| Propan-2-ol | 67-63-0 | Acetone | Urine | time End of shift at end of work- week | tion 40 mg/l | ACGIH BEI |

Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies.

SAFETY DATA SHEET according to GB/T 16483 and GB/T 17519



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| | | cabinet, furr tial exists fo | a laboratory, use a properly designed biosafety he hood, or other containment device if the poten- r aerosolization. If this potential does not exist, lined trays or benchtops. | | | | |
| | | Use explosi ment. | Use explosion-proof electrical, ventilating and lighting equip- ment. | | | | |
| Pers | onal protective equip | ment | | | | | |
| Resp | iratory protection | sure assess | local exhaust ventilation is not available or expo- ment demonstrates exposures outside the rec- | | | | |
| | Iter type face protection | : Combined p : Wear safety If the work e mists or aer Wear a face | guidelines, use respiratory protection. articulates and organic vapour type glasses with side shields or goggles. environment or activity involves dusty conditions, osols, wear the appropriate goggles. shield or other full face protection if there is a direct contact to the face with dusts, mists, or | | | | |
| Skin | and body protection | : Work uniforn Additional b task being p posable suit | m or laboratory coat. ody garments should be used based upon the erformed (e.g., sleevelets, apron, gauntlets, dis- s) to avoid exposed skin surfaces. riate degowning techniques to remove potentially ed clothing. | | | | |
| Hand | I protection | | | | | | |
| М | aterial | : Chemical-re | sistant gloves | | | | |
| R | emarks | | uble gloving. Take note that the product is flam- h may impact the selection of hand protection. | | | | |
| Hygie | ene measures | : If exposure eye flushing ing place. When using Wash conta The effective engineering appropriate industrial hy | to chemical is likely during typical use, provide systems and safety showers close to the work- do not eat, drink or smoke. minated clothing before re-use. e operation of a facility should include review of controls, proper personal protective equipment, degowning and decontamination procedures, giene monitoring, medical surveillance and the histrative controls. | | | | |

9. PHYSICAL AND CHEMICAL PROPERTIES

| Appearance | : lotion |
|-----------------|---------------------------|
| Colour | : colourless, translucent |
| Odour | : No data available |
| Odour Threshold | : No data available |
| рН | : 4.6 - 5.3 |



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| | | | | | |
| | Melting | point/freezing point | : | No data available | |
| | Initial bo range | piling point and boiling | : | No data available | |
| | Flash p | oint | : | 21.4 - 22.2 °C | |
| | Evapora | ation rate | : | No data available | |
| | Flamma | ability (solid, gas) | : | Not applicable | |
| | Flamma | ability (liquids) | : | Not applicable | |
| | | explosion limit / Upper bility limit | : | No data available | |
| | | explosion limit / Lower bility limit | : | No data available | |
| | Vapour | pressure | : | No data available | |
| | Relative | e vapour density | : | No data available | |
| | Relative | e density | : | No data available | |
| | Density | | : | No data available | |
| | Solubili Wate | ty(ies) er solubility | : | No data available | |
| | Partition octanol | n coefficient: n- | : | No data available | |
| | | nition temperature | : | No data available | • |
| | Decom | position temperature | : | No data available | |
| | Viscosit Visc | ty osity, kinematic | : | No data available | |
| | Explosi | ve properties | : | Not explosive | |
| | Oxidizir | ng properties | : | The substance or | mixture is not classified as oxidizing. |
| | Molecu | lar weight | : | No data available | 1 |
| | Particle | size | : | No data available | |

10. STABILITY AND REACTIVITY



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| | | ity al stability lity of hazardous reac- | : : | Stable under norn Highly flammable Vapours may forn | a reactivity hazard. mal conditions. Iquid and vapour. m explosive mixture with air. rong oxidizing agents. | |
| | Incomp | ons to avoid atible materials ous decomposition s | : | Heat, flames and Oxidizing agents No hazardous de | sparks. composition products are known. | |
| 11.1 | гохісо | LOGICAL INFORMAT | | l | | |
| | Exposu | re routes | : | Inhalation Skin contact Ingestion Eye contact | | |
| | Acute t | • | | | | |
| | | ssified based on availa | ble i | information. | | |
| | Produc | | | | | |
| | Acute o | oral toxicity | : | Acute toxicity estin Method: Calculation | mate: > 5,000 mg/kg on method | |
| | Acute ir | nhalation toxicity | : | Acute toxicity estin Exposure time: 4 Test atmosphere: Method: Calculatio | h dust/mist | |
| | Acute dermal toxicity | | : | Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method | | |
| | <u>Compo</u> | onents: | | | | |
| | Propan | -2-ol: | | | | |
| | Acute o | ral toxicity | : | LD50 (Rat): > 5,00 | 00 mg/kg | |
| | Acute ir | nhalation toxicity | : | LC50 (Rat): > 25 r Exposure time: 6 Test atmosphere: | h | |
| | Acute d | lermal toxicity | : | LD50 (Rabbit): > 5 | 5,000 mg/kg | |
| | salicyli | c acid: | | | | |
| | - | ral toxicity | : | LD50 (Mouse): 48 | 0 mg/kg | |
| | | | | LD50 (Rat): 891 m | ng/kg | |
| | | | | LD50 (Rabbit): 1,3 | 300 mg/kg | |
| | Acute ir | nhalation toxicity | : | LC50 (Rat): 0.9 m | g/l | |



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| | | _ | Exposure time: 1 | h |
| Acute | e dermal toxicity | : | LD50 (Rat): 2,000 |) mg/kg |
| | | | LD50 (Rabbit): 10 |),000 mg/kg |
| | um hydroxide: e inhalation toxicity | : | Assessment: Cor | rosive to the respiratory tract. |
| | nethasone: e oral toxicity | : | LD50 (Rat): > 5,0 | 00 mg/kg |
| | | | LD50 (Mouse): > | 4,500 mg/kg |
| Acute | e inhalation toxicity | : | LC50 (Rat): 0.4 m Exposure time: 4 | |
| | corrosion/irritation es skin irritation. | | | |
| Com | ponents: | | | |
| Prop Spec Resu | | : | Rabbit No skin irritation | |
| salic Resu | ylic acid: It | : | Skin irritation | |
| Sodi | um hydroxide: | | | |
| Resu | lt | : | Corrosive after 3 | minutes or less of exposure |
| betar Spec Resu | | : | Rabbit Mild skin irritation | |
| | ous eye damage/eye irr es serious eye irritation. | | on | |
| Com | ponents: | | | |
| Prop Spec Resu | | : | Rabbit Irritation to eyes, | reversing within 21 days |
| salic Spec | ylic acid: ies | : | Rabbit | |
| | | | 10/20 | |



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| Remarks | | : Severe eye irritation |
| Sodi | um hydroxide: | |
| Resu | lt | : Irreversible effects on the eye |
| Rema | arks | : Based on skin corrosivity. |
| betar | nethasone: | |
| Spec | | : Rabbit |
| Resu | lt | : No eye irritation |
| Resp | iratory or skin sensi | tisation |
| | sensitisation | niloble information |
| | | |
| - | iratory sensitisation lassified based on ava | |
| Com | ponents: | |
| Prop | an-2-ol: | |
| Test | | : Buehler Test |
| | sure routes | : Skin contact |
| Spec | | : Guinea pig |
| Meth Resu | | : OECD Test Guideline 406 : negative |
| Resu | it. | . negative |
| salic | ylic acid: | |
| Test | | : Local lymph node assay (LLNA) |
| Spec Resu | | : Mouse |
| Resu | ii. | : negative |
| | um hydroxide: | |
| Test | | : Human repeat insult patch test (HRIPT) |
| | sure routes | : Skin contact |
| Resu | IT | : negative |
| betar | nethasone: | |
| | sure routes | : Dermal |
| Spec | | : Guinea pig |
| Resu | lt | : Weak sensitizer |
| Germ | n cell mutagenicity | |
| Not c | lassified based on ava | ailable information. |
| Com | ponents: | |
| Prop | an-2-ol: | |
| • | | |

Genotoxicity in vitro

: Test Type: Bacterial reverse mutation assay (AMES)



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| | | Result: nega | tive |
| | | Test Type: Ir Result: nega | n vitro mammalian cell gene mutation test tive |
| Ge | notoxicity in vivo | cytogenetic a Species: Mo | use Route: Intraperitoneal injection |
| sal | icylic acid: | | |
| Ge | notoxicity in vitro | : Test Type: B Result: nega | acterial reverse mutation assay (AMES) tive |
| Ge | notoxicity in vivo | change Species: Mo | Route: Intraperitoneal injection |
| | | gonia Species: Mo | Route: Intraperitoneal injection |
| bet | amethasone: | | |
| Ge | notoxicity in vitro | : Test Type: B Result: nega | acterial reverse mutation assay (AMES) tive |
| | | Test Type: Ir Result: nega | n vitro mammalian cell gene mutation test tive |
| | | Test Type: C Result: posit | Chromosome aberration test in vitro |
| Ge | notoxicity in vivo | : Test Type: M cytogenetic a Species: Mo Application F Result: equiv | use Route: Oral |
| | rm cell mutagenicity - sessment | : Weight of ev cell mutagen | idence does not support classification as a germ |

Carcinogenicity

Not classified based on available information.

according to GB/T 16483 and GB/T 17519



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| | Compo | onents: | | | |
| | Propan-2-ol: Species Application Route Exposure time Method Result | | | Rat inhalation (vapour 104 weeks OECD Test Guide negative | |
| | salicyli | ic acid: | | | |
| | Species Applica Exposu NOAEL Result | ition Route ire time | | Mouse Skin contact 1 Years 2 mg/cm2 negative | |
| | - | Juctive toxicity mage the unborn child. | | | |
| | Compo | onents: | | | |
| | Propar Effects | n-2-ol: on fertility | : Test Type: Two-generation reproduce Species: Rat Application Route: Ingestion Result: negative | | |
| | Effects ment | on foetal develop- | : | Test Type: Embry Species: Rat Application Route: Result: negative | o-foetal development : Ingestion |
| | salicyli | ic acid: | | | |
| | Effects ment | on foetal develop- | : | Species: Rat Application Route Developmental To | o-foetal development : Subcutaneous oxicity: LOAEL: 380 mg/kg body weight oxicity observed., Embryo-foetal toxicity |
| | | | | Species: Rat Application Route Developmental To | o-foetal development : Oral pxicity: NOAEL: 80 mg/kg body weight on foetal development |
| | Reprod sessme | luctive toxicity - As- ent | : | Suspected of dam | aging the unborn child. |
| | betame | ethasone: | | | |
| | Effects ment | on foetal develop- | : | Species: Rabbit Application Route | : Intramuscular |



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| | | | | Toxicity: LOAEL: 0.05 mg/kg body weight city, Malformations were observed. |
| | | | Developmental | ite: Subcutaneous Toxicity: LOAEL: 0.42 mg/kg body weight lations were observed. |
| | | | Developmental | e ite: Intramuscular Toxicity: LOAEL: 1 mg/kg body weight ations were observed. |
| Repro sessm | oductive toxicity - As- nent | : | Clear evidence animal experime | of adverse effects on development, based on ents. |
| | - single exposure ause drowsiness or d | izzine | SS. | |
| <u>Comp</u> | oonents: | | | |
| | | | | |
| Propa | an-2-ol: | | | |
| Asses | ssment | : | May cause drov | vsiness or dizziness. |
| Asses STOT Cause | | | | |
| Asses STOT Cause Comp | ssment - repeated exposure es damage to organs t | | | |
| Asses STOT Cause Comp betan | ssment - repeated exposure es damage to organs t ponents: | | gh prolonged or re Pituitary gland, | |
| Asses STOT Cause Comp betan Targe | ssment - repeated exposure es damage to organs t <u>conents:</u> nethasone: | | gh prolonged or re Pituitary gland, Adrenal gland | epeated exposure. |
| Asses STOT Cause Comp betan Targe Asses | ssment - repeated exposure es damage to organs t <u>ponents:</u> nethasone: t Organs | | gh prolonged or re Pituitary gland, Adrenal gland Causes damage | epeated exposure. Immune system, muscle, thymus gland, Blood, |
| Asses STOT Cause Comp betan Targe Asses Repea | ssment - repeated exposure es damage to organs to conents: nethasone: It Organs ssment | | gh prolonged or re Pituitary gland, Adrenal gland Causes damage | epeated exposure. Immune system, muscle, thymus gland, Blood |
| Asses STOT Cause Comp betam Targe Asses Repea | ssment - repeated exposure es damage to organs to conents: methasone: t Organs ssment ated dose toxicity | | gh prolonged or re Pituitary gland, Adrenal gland Causes damage | epeated exposure. Immune system, muscle, thymus gland, Blood |
| Asses STOT Cause Comp betan Targe Asses Repea Comp Propa Specie | ssment - repeated exposure es damage to organs to conents: nethasone: t Organs ssment ated dose toxicity conents: an-2-ol: es | | ph prolonged or re Pituitary gland, Adrenal gland Causes damage exposure. | epeated exposure. Immune system, muscle, thymus gland, Blood |
| Asses STOT Cause Comp betam Targe Asses Repea Comp Propa Specie NOAE | ssment - repeated exposure es damage to organs to conents: nethasone: t Organs ssment ated dose toxicity conents: an-2-ol: es | | ph prolonged or re Pituitary gland, Adrenal gland Causes damage exposure. | epeated exposure. Immune system, muscle, thymus gland, Blood e to organs through prolonged or repeated |
| Asses STOT Cause Comp betan Targe Asses Repea Comp Propa Specie NOAE Applic | ssment - repeated exposure es damage to organs to conents: nethasone: it Organs ssment ated dose toxicity conents: an-2-ol: es EL | | ph prolonged or re Pituitary gland, Adrenal gland Causes damage exposure. Rat 12.5 mg/l | epeated exposure. Immune system, muscle, thymus gland, Blood e to organs through prolonged or repeated |
| Asses STOT Cause Comp betam Targe Asses Repea Comp Propa Specie NOAE Applic Expos | ssment - repeated exposure es damage to organs to <u>conents:</u> nethasone: it Organs ssment ated dose toxicity <u>conents:</u> an-2-ol: es EL cation Route | | ph prolonged or re Pituitary gland, Adrenal gland Causes damage exposure. Rat 12.5 mg/l inhalation (vapo | epeated exposure. Immune system, muscle, thymus gland, Blood e to organs through prolonged or repeated |
| Asses STOT Cause Comp betam Targe Asses Repea Comp Propa Specia NOAE Applic Expose salicy Specia | ssment - repeated exposure es damage to organs t conents: methasone: t Organs ssment ated dose toxicity conents: an-2-ol: es EL cation Route sure time vlic acid: es | | ph prolonged or re Pituitary gland, Adrenal gland Causes damage exposure. Rat 12.5 mg/l inhalation (vapo 104 Weeks | epeated exposure. Immune system, muscle, thymus gland, Blood e to organs through prolonged or repeated |
| Asses STOT Cause Comp betan Targe Asses Repea Comp Propa Specia NOAE Specia NOAE | ssment - repeated exposure es damage to organs t conents: methasone: t Organs ssment ated dose toxicity conents: an-2-ol: es EL cation Route sure time vlic acid: es | | ph prolonged or re Pituitary gland, Adrenal gland Causes damage exposure. Rat 12.5 mg/l inhalation (vapo 104 Weeks | epeated exposure. Immune system, muscle, thymus gland, Blood e to organs through prolonged or repeated |

according to GB/T 16483 and GB/T 17519



Betamethasone / Salicylic Acid Lotion Formulation

| Revision Date: 2021/04/09 | SDS Number:Date of last issue: 2020/10/101832968-00012Date of first issue: 2017/07/13 |
|---------------------------|---|
| es L ation Route | : Rat : 500 mg/kg : Oral : 3 d |
| t Organs | : Liver |
| nethasone: | |
| es | : Rabbit |
| | : 0.05 % |
| | : Skin contact : 10 - 30 d |
| | : Pituitary gland, Immune system, muscle |
| Congano | |
| es | : Rat |
| L | : 0.05 % |
| | : Skin contact |
| | 8 Weeks |
| t Organs | : thymus gland |
| es | : Mouse |
| L | : 0.1 % |
| ation Route | : Skin contact |
| ure time | : 8 Weeks |
| t Organs | : thymus gland |
| es | : Dog |
| L | : 0.05 mg/kg |
| | : Oral |
| ure time | : 28 d |
| t Organs | : Blood, thymus gland, Adrenal gland |
| | es L ation Route ure time t Organs nethasone: es L ation Route ure time t Organs es L ation Route ure time t Organs es L ation Route ure time t Organs es L ation Route ure time t Organs |

Experience with human exposure

Components:

salicylic acid:

| Skin contact Eye contact Ingestion | | Symptoms: Skin irritation Symptoms: Severe irritation Symptoms: Gastrointestinal discomfort, hearing loss, Dizzi- ness, electrolyte imbalance |
|--|---|--|
| betamethasone: | | |
| Inhalation Skin contact | : | Target Organs: Adrenal gland Symptoms: Redness, pruritis, Irritation |



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| | | | | |

12. ECOLOGICAL INFORMATION

| Ecotoxicity | | |
|---|---|---|
| Components: | | |
| Propan-2-ol: | | |
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 10,000 mg/l Exposure time: 24 h |
| Toxicity to microorganisms | : | EC50 (Pseudomonas putida): > 1,050 mg/l Exposure time: 16 h |
| salicylic acid: | | |
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): 1,380 mg/l Exposure time: 96 h Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 870 mg/l Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chron-ic toxicity) | : | NOEC (Daphnia magna (Water flea)): 10 mg/l Exposure time: 21 d |
| betamethasone: | | |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Americamysis): > 50 mg/l Exposure time: 96 h |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility |
| | | NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility |
| Toxicity to fish (Chronic tox- icity) | : | NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l Exposure time: 32 d Method: OECD Test Guideline 210 |



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|----------------|---|----|---|---|
| | | | NOEC (Oryzias la Exposure time: 21 Method: OECD Te | |
| aqu | Toxicity to daphnia and other aquatic invertebrates (Chron-ic toxicity) | | NOEC (Daphnia magna (Water flea)): 8 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 | |
| M-F toxic | actor (Chronic aquatic city) | : | 1,000 | |
| Per | sistence and degradabili | ty | | |
| <u>Cor</u> | nponents: | | | |
| | pan-2-ol: degradability | : | Result: rapidly de | gradable |
| BOI | BOD/COD | | BOD: 1.19 (BOD5 | i)COD: 2.23BOD/COD: 53 % |
| Bio | accumulative potential | | | |
| <u>Cor</u> | nponents: | | | |
| Part | pan-2-ol: tition coefficient: n- anol/water | : | log Pow: 0.05 | |
| Part | cylic acid: tition coefficient: n- anol/water | : | log Pow: 2.25 | |
| Part | amethasone: tition coefficient: n- anol/water | : | log Pow: 2.11 | |
| | bility in soil data available | | | |
| | er adverse effects data available | | | |

13. DISPOSAL CONSIDERATIONS

| Disposal methods | | |
|---|---|---|
| Waste from residues Contaminated packaging | : | Dispose of in accordance with local regulations. Empty containers should be taken to an approved waste han- dling site for recycling or disposal. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or ex- pose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product. |



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14. TRANSPORT INFORMATION

International Regulations

| UNRTDG UN number Proper shipping name Class Packing group Labels | : | UN 1219 ISOPROPANOL SOLUTION 3 II 3 |
|---|---|---|
| IATA-DGR UN/ID No. Proper shipping name Class Packing group Labels Packing instruction (cargo aircraft) Packing instruction (passen- ger aircraft) | : | UN 1219 Isopropanol solution 3 II Flammable Liquids 364 353 |
| IMDG-Code UN number Proper shipping name Class Packing group Labels EmS Code Marine pollutant | : | UN 1219 ISOPROPANOL SOLUTION (betamethasone) 3 II 3 F-E, S-D yes |

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

Not applicable for product as supplied.

National Regulations

GB 6944/12268

| UN number | : | UN 1219 |
|----------------------|---|----------------------|
| Proper shipping name | : | ISOPROPANOL SOLUTION |
| Class | : | 3 |
| Packing group | : | II |
| Labels | : | 3 |
| | | |

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

National regulatory information Law on the Prevention and Control of Occupational Diseases



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Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals : Listed

Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218)No. / CodeChemical name / CategoryW5.3Flammable liquidsThreshold quantity

| AICS | : | not determined |
|-------|---|----------------|
| DSL | : | not determined |
| IECSC | : | not determined |

16. OTHER INFORMATION

Further information

| Sources of key data used to compile the Safety Data Sheet | : | Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen- cy, http://echa.europa.eu/ | | |
|---|-----|--|--|--|
| Date format | : | yyyy/mm/dd | | |
| Full text of other abbreviations | | | | |
| ACGIH ACGIH BEI CN OEL | : : | USA. ACGIH Threshold Limit Values (TLV) ACGIH - Biological Exposure Indices (BEI) Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents. | | |
| ACGIH / TWA ACGIH / STEL ACGIH / C CN OEL / PC-TWA CN OEL / PC-STEL CN OEL / MAC | | 8-hour, time-weighted average Short-term exposure limit Ceiling limit Permissible concentration - time weighted average Permissible concentration - short term exposure limit Maximum allowable concentration | | |
| ······································ | • | | | |

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Or-



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ganisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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