ACNE THERAPY

Date: October 14, 2016

FOREWORD

This monograph describes the requirements necessary to receive marketing authorization (a Natural Product Number (NPN) or a Drug Identification Number (DIN)) for a product intended to treat/manage acne.

Acne therapy products are classified as natural health products (NHPs) if they contain an ingredient listed in Table 1 and do not contain any ingredient listed in Table 2. Applicants seeking to obtain a NPN can access the appropriate forms and guidance at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/form/index_e.html.

Acne therapy products are classified as drugs if they contain an ingredient listed in Table 2. Applicants seeking to obtain a DIN can access the appropriate forms and guidance at http://hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/index_e.html.

Note: The solidus (/) indicates that the terms and/or the statements are synonymous. Either term or statement may be selected by the applicant. Text in parentheses is additional optional information which can be included on the Product Licence Application form and label at the applicant’s discretion.

Medicinal Ingredient(s)

Table 1: NHP medicinal ingredients and associated doses

<table>
<thead>
<tr>
<th>Proper name(s)</th>
<th>Common name(s)</th>
<th>Source material(s)</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salicylic acid, 2-Hydroxybenzoic acid</td>
<td>Salicylic acid</td>
<td>Salicylic acid CAS No. 69-72-7</td>
<td>0.5-2%</td>
</tr>
<tr>
<td>Sulfur</td>
<td>Sulfur</td>
<td>Sulfur CAS No. 7704-34-9</td>
<td>3-10%^4</td>
</tr>
<tr>
<td>1,3-Benzenediol Resorcinol</td>
<td>Resorcinol</td>
<td>Resorcinol CAS No. 108-46-3</td>
<td>2%^*</td>
</tr>
<tr>
<td>1,3-Benzenediol, monoacetate Resorcinol monoacetate</td>
<td>Resorcinol monoacetate</td>
<td>Resorcinol monoacetate CAS No. 102-29-4</td>
<td>3%^*</td>
</tr>
</tbody>
</table>

* Resorcinol and Resorcinol monoacetate are not permitted as single medicinal ingredients and must be in combination with 3-8 % sulfur (FDA 2010).

^1 At least one of the following references was consulted: O’Neil et al. The Merck Index Online 2015; USP 38

^2 At least one of the following references was consulted: O’Neil et al. The Merck Index Online 2015; USP 38

^3 FDA Final Rule 2015; 21 CFR part 333 Topical Antimicrobial Drug Products for Over-The-Counter Human use

^4 The appropriate dosage range for sulfur in combination with resorcinol or resorcinol monoacetate is 3-8 % (FDA 2010)
Table 2: Drug medicinal ingredient and associated dose

<table>
<thead>
<tr>
<th>Medicinal ingredient preferred name</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzoyl peroxide</td>
<td>2.5-5%</td>
</tr>
</tbody>
</table>

Permitted Combinations of Medicinal Ingredients

The only permitted combinations are sulfur + resorcinol or resorcinol monoacetate (FDA 2010):

Sulfur: 3 - 8 % + Resorcinol: 2 %
Sulfur: 3 - 8 % + Resorcinol monoacetate: 3 %

Additional notes: Products containing resorcinol or resorcinol monoacetate in combination with sulfur cannot be indicated as body cleansers or as a face wash.

Route of administration

Topical

Dosage form(s)\(^5\)

For all products (drugs and NHPs):

Acceptable dosage forms include: Lotion, cream, gel, solution, liquid, ointment, wipe, aerosol and paste.

For NHPs only:

Acceptable dosage forms also include: Bar soap and sponge.

Use(s) or Purpose(s)\(^6\)

Statement(s) to the effect of:

For all products:

- For the treatment/management of acne.

One or more of the following statements may also be included:

\(^{5}\) Consult Appendix 1 for dosage forms that fall outside the scope of the monograph.
\(^{6}\) Consult Appendix 2 for uses or purposes that fall outside the scope of the monograph.
• Helps treat acne pimples (Optional: “and allow skin to heal”).
• Dries and helps clear up acne pimples (Optional: “and allow skin to heal”).
• Reduces the number and/or severity of acne pimples (Optional: “and allow skin to heal”).
• Penetrates pores to control (reduce) acne pimples.
• Helps keep skin clear of new acne pimples.
• Helps prevent new acne pimples from forming.

For products containing benzoyl peroxide, the following statement may be made:

• Prevents and kills acne bacteria.

Unacceptable use(s) or purpose(s):

Statement(s) to the effect of:
• Controls oil (oily skin).
• Cures acne.

Directions for use

Statement(s) to the effect of:

For all products:

• For New Users: Apply product to a small area once a day for three days to test if you are sensitive to this product.
• If no discomfort occurs, cover the entire affected area with a thin layer.
• Start with one application daily, then gradually increase to two or three times daily, if needed.
• If dryness or peeling occurs, reduce application to once a day or every other day.

For products intended to be applied on the skin and left on:

• Cleanse skin thoroughly before applying the product.

For products intended to be applied and rinsed from the skin:

• Rinse off (optional: after x minutes).

Duration of use

No statement required.
Risk information

Caution(s) and Warning(s):

Statement(s) to the effect of:

For all products:

- For external use only. Keep out of reach of children. If swallowed, call a Poison Control Centre or get medical help right away.
- Skin irritation and dryness are more likely to occur when using another topical acne product at the same time. If irritation occurs, use only one product at a time.
- Avoid contact with eyes; if contact occurs, rinse thoroughly with water.
- For more severe cases, and/or if improvement is not apparent within 6-8 weeks, consult a health care professional.

For products containing Sulfur or Sulfur in combination with Resorcinol or Resorcinol Monoacetate:

- Apply only to areas with acne.

For products containing Benzoyl Peroxide:

- Avoid contact with lips, mouth, and nostrils; if contact occurs, rinse with water.
- Avoid contact with hair and dyed fabrics, which may be bleached by this product.
- Avoid unnecessary sun exposure and use a sunscreen.

Contraindication(s)

For products containing Sulfur or Sulfur in combination with Resorcinol or Resorcinol Monoacetate:

- Do not use
  - on broken skin.
  - on large areas of the skin.

For products containing Benzoyl Peroxide:

- Do not use if you
  - have very sensitive skin.
  - are allergic to benzoyl peroxide or any other ingredient in the product.

Known Adverse Reaction(s)

For all products:
If you develop severe irritation, burning or itching of the skin, discontinue use and consult a health care professional.

If you develop hives, swelling of eyes and mouth, blistering or difficulty breathing, get medical help right away.
<table>
<thead>
<tr>
<th>Medicinal ingredient</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salicylic acid XX %</td>
<td>Acne Treatment</td>
</tr>
</tbody>
</table>

### Uses
- Treatment/management of acne:
  - helps treat acne pimples
  - helps keep skin clear of new acne pimples
  - dries and helps clear up acne pimples
  - reduces the number and/or severity of acne pimples
  - helps prevent new acne pimples from forming
  - penetrates pores to control acne pimples.

### Warnings
- For external use only.

#### When using this product
- avoid contact with eyes; if contact occurs, rinse thoroughly with water
- skin irritation and dryness are more likely to occur when using another topical acne product at the same time. If irritation occurs, use only one product at a time.

#### Stop use and ask a doctor if
- you develop severe irritation, burning or itching of the skin
- for more severe cases and/or if improvement is not apparent within 6 to 8 weeks.
- If you develop hives, swelling of eyes and mouth, blistering or difficulty breathing, get medical help right away.

#### Keep out of reach of children.
If swallowed, call a Poison Control Centre or get medical help right away.

### Directions
- cleanse skin thoroughly before applying the product
- for new users: apply product to a small area once a day for three days to test if you are sensitive to this product
- if no discomfort occurs, cover the entire affected area with a thin layer
- start with one application daily, then gradually increase to two or three times daily, if needed
- if dryness or peeling occurs, reduce application to once a day or every other day.

### Other information
(if no information here, delete this heading)

### Nonmedicinal ingredients
<List all NMIs>

### Questions?
Call 1-XXX-XXX-XXXX (or other contact information)
### Drug Facts

<table>
<thead>
<tr>
<th>Active ingredient (in each dosage unit)</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzoyl Peroxide XX %</td>
<td>Acne Treatment</td>
</tr>
</tbody>
</table>

#### Uses
- Treatment/management of acne:  
  - prevents and kills acne bacteria  
  - helps treat acne pimples  
  - helps keep skin clear of new acne pimples  
  - dries and helps clear up acne pimples  
  - reduces the number and/or severity of acne pimples  
  - helps prevent new acne pimples from forming  
  - penetrates pores to control acne pimples.

#### Warnings

**For external use only.**

**Do not use if you**
- have very sensitive skin  
- are allergic to benzoyl peroxide or any other ingredient in this product.

**When using this product**
- avoid unnecessary sun exposure and use a sunscreen  
- avoid contact with eyes, lips, nostrils and mouth. If contact occurs, rinse thoroughly with water  
- avoid contact with hair and dyed fabrics, which may be bleached by this product  
- skin irritation and dryness are more likely to occur when using another topical acne product at the same time. If irritation occurs, use only one product at a time.

**Stop use and ask a doctor if**
- you develop severe irritation, burning or itching of the skin  
- for more severe cases and/or if improvement is not apparent within 6 to 8 weeks.

- If you develop hives, swelling of eyes and mouth, blistering or difficulty breathing, get medical help right away.

**Keep out of reach of children.** If swallowed, call a Poison Control Centre or get medical help right away.

#### Directions
- cleanse skin thoroughly before applying the product  
- for new users: apply product to a small area once a day for three days to test if you are sensitive to this product  
- if no discomfort occurs, cover the entire affected area with a thin layer  
- start with one application daily, then gradually increase to two or three times daily, if needed  
- if dryness or peeling occurs, reduce application to once a day or every other day.

#### Other information
- (if no information here, delete this heading)

#### Inactive ingredients
- <List all NMIs>

#### Questions?
Call 1-XXX-XXX-XXXX (or other contact information)

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7 The regulatory amendment for a Fact Table for non-prescription drug products would come into force three years after the day of registration in *Canada Gazette* Part II (June 13, 2017).

Non-medicinal ingredients

Non-medicinal ingredients must be chosen from the current Natural Health Products Ingredients Database (NHPID)\(^8\) and must meet the limitations outlined in that database, the Food and Drug Regulations (FDR)\(^9\), the Herbs used as Non-medicinal Ingredients in Non-prescription Drugs for Human Use\(^10\) policy, and/or the current Cosmetic Ingredient Hotlist\(^11\), when relevant.

Specifications

For products containing ingredients listed in Table 1: NHP medicinal ingredients and associated doses:


For products containing the ingredient from Table 2: Drug medicinal ingredient:

Health Canada’s Guidance Document: Labelling of Pharmaceutical Drugs for Human Use should be consulted for applicable labelling requirements.

Products must comply with the requirements in the Food and Drugs Act and associated Regulations. It is also noted that all products are subject to Part C, Division 2 of the Food and Drug Regulations.

When applicable, the medicinal ingredient(s) should comply with the specifications outlined in the associated monograph from the standards listed on Schedule B to the Food and Drugs Act.

Where no Schedule B monograph exists for the finished product’s dosage form, specifications should be similar to those of a comparable compendial dosage form, demonstrating the product’s identity, potency, purity and quality.

Products that contain medicinal ingredients not included in Table 2 may be considered New Drugs as per section C.08.001 of the Food and Drug Regulations.

Specifications for Drug Facts table can be found under section 2.4.4 of the guidance document: Good Label and Package Practice Guide for Non-prescription Drugs and Natural Health Products.

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8 Health Canada 2015
9 Government of Canada 2015
10 Health Canada 1995
11 Health Canada 2014a
References


Appendix 1: Dosage forms that fall outside the scope of this monograph

The following dosage forms for acne products are associated with indications of use that fall outside the scope of this monograph:

- Sponge (for drug products)
- Shampoo
- Bar soap (for drug products)

These, as well as all other dosage forms not identified as acceptable in the ‘Dosage form(s)’ section of this document, require assessment outside of the monograph stream.

Appendix 2: Applications that fall outside the scope of this monograph

Applications for products that recommend a sequential treatment regime or products co-packaged with another drug, natural health product or cosmetic product (as defined in the Guidance Document: Labelling of Pharmaceutical Drugs for Human Use) will be reviewed outside the monograph.

Any change to the manufacturing process that impacts the safety and efficacy of the ingredients, such as the use of novel technology (e.g. nanotechnology), requires supporting data and will be reviewed outside the monograph.