

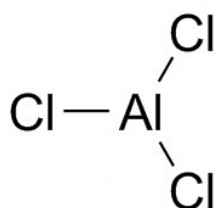
Outline of the Amendment to the Cabinet Order  
on the Deleterious Substances Designation Order

1. Aluminium(III) chloride and preparations containing this substance as Deleterious Substance.

(1) Chemical name

Aluminium(III) chloride (CAS No. :7446-70-0)

(2) Chemical structure

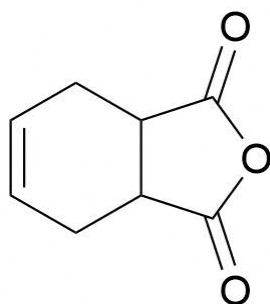


2. Cyclohexane-4-en-1,2-dicarboxylic anhydride and preparations containing this substance as Deleterious Substance.

(1) Chemical name

Cyclohexane-4-en-1,2-dicarboxylic anhydride (CAS No. :85-43-8)

(2) Chemical structure

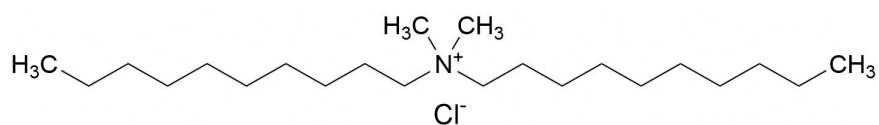


3. Didecyl(dimethyl)ammonium chloride and preparations containing this substance more than 0.4% as Deleterious Substance.

(1) Chemical name

Didecyl(dimethyl)ammonium chloride (CAS No. :7173-51-5)

(2) Chemical structure

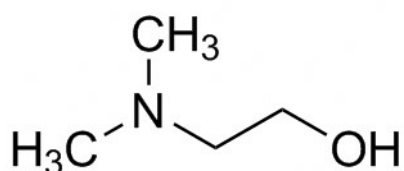


4. 2-(Dimethylamino)ethanol and preparations containing this substance more than 3.1% as Deleterious Substance.

(1) Chemical name

2-(Dimethylamino)ethanol (CAS No. :108-01-0)

(2) Chemical structure

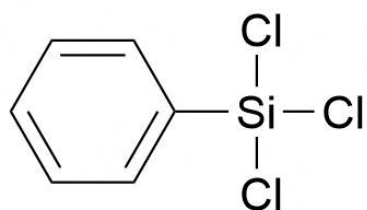


5. Trichloro(phenyl)silane and preparations containing this substance as Deleterious Substance.

(1) Chemical name

Trichloro(phenyl)silane (CAS No. :98-13-5)

(2) Chemical structure

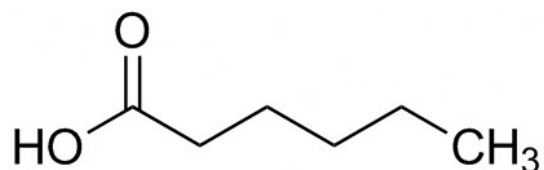


6. Hexanoic acid and preparations containing this substance more than 11% as Deleterious Substance.

(1) Chemical name

Hexanoic acid (CAS No. :142-62-1)

(2) Chemical structure

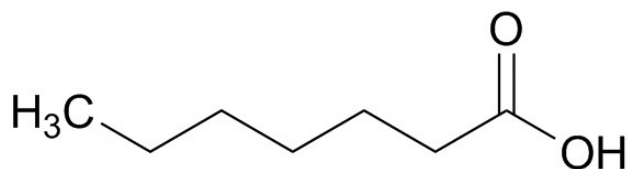


7. Heptanoic acid and preparations containing this substance more than 11% as Deleterious Substance.

(1) Chemical name

Heptanoic acid (CAS No. :111-14-8)

(2) Chemical structure

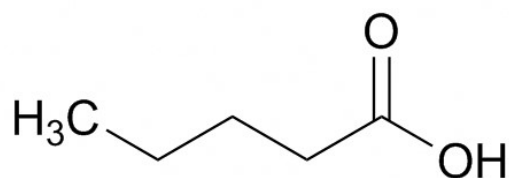


8. Pentanoic acid and preparations containing this substance more than 11% as Deleterious Substance.

(1) Chemical name

Pentanoic acid (CAS No. :109-52-4)

(2) Chemical structure



※ To drop Butyric acid and preparations containing this substance more than 3% as Deleterious Substance, and changes into 8 substances.

## **Japan's reply to the comments of IOFI regarding the WTO notification G/TBT/N/JPN/624**

Japan appreciates the comments on “Amendment to the Poisonous and Deleterious Substances Designation Order” notified to the World Trade Organization (WTO) as G/TBT/N/JPN/624.

1. To provide detailed implementation rules and measures of the Amendment prior to the enforcement.

We provided food related associations including Japan Margarine, Shortening and Lard Industries Association, food business operators and general consumers with the content of the revision concerned.

Concrete pieces of information provided are as follows (only in Japanese):

- Amendment to the Poisonous and Deleterious Substances Designation Order (Cabinet Order No.31 of June 19, 2019. “*KAMPO*” (Official Gazette))

<https://search.npb.go.jp/kanpou/?uji.pageid=5&uji.verb=image&articleName=20190619kg0004000020seire&dspPage=29&subWindowId=eMJcaRlo&totalPage=30&uji.verbs=text%2Cimage&uji.id=mainbody&uji.bean=jp.go.npb.haishin.web.bean.article.ArticleResultListEventBean>

- Amendment to the Poisonous and Deleterious Substances Designation Order (Notification YakuSeiHatsu 0619 No.1 of June 19, 2019)

<https://www.mhlw.go.jp/hourei/doc/tsuchi/T190619I0020.pdf>

- Public consultation (summary)

<https://search.e-gov.go.jp/servlet/PcmFileDownload?seqNo=0000186290>

2. To grant a sufficiently long transitional period before the Amendment is fully implemented.

Generally, we decided the transitional period of this amendment is from 1<sup>st</sup> July 2019 to 30<sup>th</sup> September 2019, taking the burden on Poisonous and Deleterious Substances business operators into consideration.

Regarding these substances we are going to designate them as deleterious ones, we started the examination for designation more than one year ago and published information on the web page of Poisonous Substances and Deleterious Substances sectional meeting of the Pharmaceutical Affairs and Food Sanitation Council. (Only in Japanese)

- [https://www.mhlw.go.jp/stf/shingi/shingi-yakuji\\_127875.html](https://www.mhlw.go.jp/stf/shingi/shingi-yakuji_127875.html)

3. To clarify the scope of “preparations”. For instance, certain food products may contain much higher concentration of the fatty acids as regulated in this Amendment (e.g. enzymatically processed cheese) – Actually, would this type of products also fall under the scope of PDSCA?

Products containing Poisonous Substances or Deleterious Substances are regarded as "formulation".

Out of four fatty acids, Pentanoic acid, Hexanoic acid and Heptanoic acid are going to be designated as scheduled.

However, we decided to give up designation of Butyric acid this time, because we realized that our examination was insufficient taking into account of the opinion received during public consultation.

Therefore, we decided to examine more data including concentration at which the safety to a human body is assured, and decided not to designate Butyric acid as deleterious substance this time.

4. To establish appropriate analytical methods for the detection of violations (i.e., exceeding the concentration thresholds set forth by this Amendment).

Business operators who manufacture, import or sale, etc. of products need to judge whether substances contained fall under Poisonous Substances or Deleterious Substances.

Since the composition of Poisonous or Deleterious Substances and others differs from product by product, it is difficult for us to establish general analytical methods for all of the products.

We ask each business operators to grasp the amount of chemical substances used in their products by cooperation with companies from which they purchase source materials, and by appropriate sharing of information, and we ask them to take action needed based on the provision of the Poisonous and Deleterious Substances Control Act.