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### Introduction

Tartrazine, also known as FD&C Yellow no 5, is an artificially produced colouring. It is not a new invention - in 1884 tartrazine was one of the first synthetic pigments to be patented. Today, it is a common additive found in foods, beverages, medicines, vitamin supplements, cosmetics, toiletries and other non food products.

It is easy to think of tartrazine as a simple product adding only colour. The reality is quite different. Whilst the primary purpose of tartrazine is to add to colour to food, drugs, drinks, creams and lotions, it also introduces into your body a range of chemicals. Tartrazine is not just a colour, it is a complex product containing many different chemical compounds. You can read a full technical specification in the Appendix: Just What is Tartrazine.

Out of all the food colourings in current use, tartrazine has been the one most implicated in causing adverse reactions. Reports in the medical literature date back to the 1950s. For example, in 1959 Lockey reported on 3 people with a history of rashes that occurred when taking tartrazine coloured drugs (18).

Tartrazine often causes adverse reactions such as recurrent urticaria, angioedema, and asthma and is frequently implicated in behavioural problems (7). The most common symptoms linked with a tartrazine sensitivity are urticaria and asthma (10) but, like with any food or chemical, symptoms are very individual specific.

It has also been found that many individuals who are allergic to anti-inflammatory drugs, such as aspirin, also experience adverse reactions to tartrazine.

This booklet provides you with a summary of the main research studies that have identified tartrazine as causing adverse reactions in some individuals. Studies that have been carried out on animals have not been included because, ethical concerns aside, the results are not directly transferable to humans.

I have also not included studies that 'disprove' tartrazine problems and lay the blame on over protective parents and/or on

psychological problems. These studies often provide more information on how not to conduct research rather than on the health effects of food additives.

The reality is that tartrazine, like some other food additives, does cause problems for some children and adults. My concern is to present the facts as they are currently known.

Sharla Race

# Symptoms

All of the symptoms below have been linked with tartrazine sensitivity. Please note that each and every symptom listed could have a different cause. It is also the case that other symptoms, not listed, may also be triggered by tartrazine in some individuals.

> Angioedema Asthma **Behavioural Problems Blurred Vision** Coughing Dermatitis General weakness Joint Pain Learning Difficulties Melkersson-Rosenthal Syndrome Migraine Nasal obstruction Paresthesias Pruritus Purpura Rhinitis Rhinorrhea Sleep Problems Urticaria Vasculitis Vomiting

### **Tartrazine in Medicines**

Tartrazine is often found in medicines where its only purpose is to provide colour and so it is classed as a 'non active' ingredient. Sadly, for many, it becomes a very 'active' ingredient providing many unwanted symptoms.

A 1989 study set out to assess the prevalence of colourings and preservatives in drug formulations in the United Kingdom. Pharmaceutical manufacturers were asked to supply data on drug formulations especially colourings and preservatives. In total, 2204 drug formulations were analysed. They were found to contain 419 different additives, 52 of these were colourings and preservatives that have been implicated in adverse reactions. Tartrazine was the fourth most commonly occurring colouring, it was present in 124 drug formulations (31).

A similar study in Switzerland found tartrazine to be present in 4.9% of 1,467 frequently administered drug formulations (17).

### When is a drug side effect not real?

When the reaction is caused by a non active ingredient such as tartrazine.

Bhatia found that 83 of 2210 individuals being treated with drugs containing tartrazine were allergic to tartrazine. Once the offending drugs were stopped, the symptoms subsided within 24 to 48 hours. None of the 83 reacted to brands of the same drug that did not contain tartrazine. It is interesting to note that 13.2% had a previous history of problems with tartrazine (that this had not been checked before the drugs were prescribed is worrying), and 15.7% had a history of aspirin sensitivity (5).

A 'fixed drug eruption' (a skin condition that recurs in the same place whenever a particular medication is taken) was found to be caused by a sensitivity to tartrazine, a non active ingredient in the medicine, in an 11 year old girl. For this child the skin condition always arose on the back of her left hand (26). A 1996 study by Bhatia found that allergy to psychiatric drugs that contained tartrazine, especially anti-depressants, was not uncommon. In the case of 20 individuals using alprazolam containing tartrazine adverse reactions were experienced. When the same medication was prescribed without tartrazine no adverse reactions were experienced (4).

Pohl et al reported on five individuals who experienced allergic type reactions to tartrazine used in antidepressants. They noted that the identified frequency of tartrazine sensitivity was much higher than the previously reported frequency of six in 1,000 (30).

### Asthma

In the medical literature, asthma is one of the most common conditions linked with tartrazine sensitivity. Summaries of some of the studies are given below:

- Four children with aspirin induced asthma were tested for sensitivity to other substances including tartrazine. Two of the children tested positive for reactions to tartrazine (6).
- A study, by Freedman of 272 people with asthma, found that thirty (11%) had their symptoms exacerbated by orange drinks. Fourteen of these underwent provocation tests for sulphur dioxide, sodium benzoate and tartrazine which are present in orange drinks.

Eight reacted to sulphur dioxide, four to sodium benzoate and one to tartrazine. Prior inhalation of sodium cromoglycate by four patients inhibited the reaction to these substances (12).

- Ten asthmatic children with a history of cough or wheeze after orange drinks, were tested for tartrazine sensitivity. On separate days, either oral tartrazine (1 mg) or a placebo capsule were used in the tests. Bronchial reactivity was measured before the test and at 30 and 60 minutes after ingestion. They found that there was no change in baseline lung function after tartrazine but histamine sensitivity increased significantly in four of the children (13).
- One-hundred and forty asthmatics were tested for sensitivity to acetylsalicylic acid (aspirin) and/or tartrazine. About one quarter displayed a positive reaction to one of the two substances. They also found that in most cases where there was sensitivity to acetylsalicylaic acid there was also sensitivity to tartrazine (42).
- In 1958, Speer reported that tartrazine and other chemical dyes, cause asthma in some children (41).

- Spector et al found that in asthma sufferers who were aspirin intolerant there was a possibility of also being sensitive to tartrazine (25% of those studied). In asthmatics who were aspirin tolerant there were no attacks triggered by tartrazine (40).
- A literature review by MacCara found that between 4% and 14% of individuals with asthma or allergies or both and from 7% to 20% of those who are sensitive to acetylsalicylic acid may react to tartrazine (20).
- Hong et al found that asthmatic attacks can be exacerbated or triggered by tartrazine sensitivity (14).

# Hyperactivity

There has been much written over the years, since Feingold's work in the 1970s, on the links between hyperactivity and food colourings. Much is still disputed but each year thousands of parents find marked improvement in their children's behaviour when these substances are removed from their diets.

The study summaries below are some of the ones that specifically tested tartrazine.

 An Australian study placed 200 children with suspected hyperactivity on a six week diet free from synthetic food colourings. The parents of 150 of the children noted improvements in their children, and deterioration in their behaviour on the introduction of foods that contained synthetic colourings.

A further study of 34 other children was then undertaken, 23 of these were suspected of reacting to food colours, 11 were unknown reactors. The colour used in this test was tartrazine, Nineteen out of the 23, and 3 out of the 11, reacted to the test doses. The reactions were irritability, restlessness and sleep disturbance. Interestingly, this study also had 20 control individuals and 2 of these also reacted in the same way.

The testing was done with varying levels of tartrazine and the reactions were found to be dose related - the greater the amount the longer the effect would last (34).

 In 1988, Rowe carried out a study with hyperactive children. Fifty five children were placed on the Feingold diet for 6 weeks. Forty of these children (72.7%) demonstrated improved behaviour and 26 (47.3%) remained improved when the diet was less stringent over a period of 3-6 months.

The parents of 14 of the children claimed that a particular cluster of behaviours was associated with the ingestion of foods containing synthetic colourings. Eight of these

children were kept on a diet free from synthetic additives and were challenged on a regular basis with either a placebo or 50mg of tartrazine or carmoisine.

Two of the children demonstrated significant reactions most notably irritability, restlessness and sleep disturbance. One of them did not have inattention as a feature. Rowe makes the observation that studies involving strict criteria based on 'attention deficit disorder' may miss children who do experience behavioural changes as a result of additives (33).

 Swanson and Kinsbourne challenged 40 children with tartrazine and then tested them with paired associate learning tests. They found that the performances of the children identified as hyperactive were impaired on the days tartrazine was ingested and not on the days that the placebo was used. The control group of children who were not classed as hyperactive did not react to tartrazine (43).

# **Skin Conditions**

Urticaria is the main skin condition that has been associated with tartrazine sensitivity but links have also been found to dermatitis and progressive pigmented purpura.

### Urticaria

- A study of 36 individuals, 29 women and 7 men, with chronic urticaria identified sensitivity to additives as a common problem. The additives tested included tartrazine, sodium metabisulfite, potassium metabisulfite, and sodium bisulfite. Tartrazine was the additive that caused most problems (15).
- In a study of thirty three individuals with urticaria and angioneurotic oedema, ten were found to be intolerant of at least one of the three additives tested - sodium benzoate, sodium metabisulfite and tartrazine. The largest number of positive reactions were to sodium benzoate, followed by tartrazine (22).
- In 1975, Settipane and Pudupakham carried out double blind challenge tests with 2 individuals with chronic urticaria and with 18 others who developed urticaria after ingesting tartrazine. They found that 1 of the 2 with urticaria, and 2 of the other 18, experienced adverse reactions to tartrazine when tested with amounts between 0.22 and 0.44 mg - the amount usually found in a colour coded pill (38).
- Baumgardner presents details of an individual with urticaria that was triggered by tartrazine (2).
- Lockey noted that Tartrazine, and other permitted colour additives may have an exacerbating effect in both chronic urticaria and asthma and that the only way of establishing if this is the case is by the administration of test doses (19).

 Thirty Eight people diagnosed with chronic urticaria, without an identifiable cause, were evaluated for food and drug additive sensitivity, 20 had suffered with urticaria for one year or more. Ten had a history of aspirin intolerance, but elimination of aspirin did not relieve the urticaria.

A double-blind crossover challenge with 0.22 mg of tartrazine, and a control, was carried out and tartrazine sensitivity was found in 3 individuals. Two of those with an aspirin problem were also sensitive to tartrazine (37).

- In a study of individuals with chronic urticaria, Doeglas found that aspirin sensitives were often also sensitive to tartrazine (11).
- Tartrazine was found to be one of the most common additives to trigger urticaria in cases where the condition was triggered by intolerance factors (36).

### Dermatitis

- Twenty five children with atopic dermatitis were studied. All the children reacted to at least one additive, 2 reacted to tartrazine (45).
- Tartrazine sensitivity was confirmed in 1 out of 12 children with atopic dermatitis (9).

### **Progressive Pigmented Purpura**

Progressive pigmented purpura, also known as Schamberg's disease, is a type of capillaritis in which crops of red-brown flat patches with cayenne pepper spots on their borders appear for no apparent reason. Although most common on the lower legs, Schamberg's can arise on any part of the body. It is usually irregularly distributed on both sides with few or many patches. This condition, for one individual, was found to be triggered by tartrazine (16).

## **Other Symptoms**

- Settipane notes that the 'Restaurant syndromes' can be caused by five major factors: food allergens, sulphites, monosodium glutamate (MSG), tartrazine, and seafood poisoning. He suggests that tartrazine sensitivity should be considered if an individual reacts with breathing problems and urticaria and has a history of aspirin intolerance (39).
- Marques et al identified tartrazine as a trigger agent in some cases of **rhinitis** (21).
- Novembre et al present two cases were tartrazine and benzoates were triggers for headaches, migraine, overactivty, concentration and learning difficulties, and joint pain (25).
- **Purpuric vasculitis** has been linked to tartrazine sensitivity (28).
- Melkersson-Rosenthal Syndrome is syndrome often beginning in childhood or adolescence, characterised by chronic facial oedema, recurrent peripheral facial paralysis, sometimes fissured tongue, and certain eye problems. It is also called granulomatous cheilitis or cheilitis granulomatosa.

Pachor et al present details of the Melkersson-Rosenthal syndrome that occurred in an adult who experienced intolerance to sodium benzoate and tartrazine. The main symptoms experienced included facial swelling and gum enlargement. All the symptoms went away when the two food additives were excluded from the diet (27).

 Pellegrin reported on two people who developed an allergy to tartrazine. Their symptoms were mainly related to the skin and mucous membranes (29).  In a study by Neuman et al, oral administration of 50 mg tartrazine to 122 people with a variety of allergic disorders caused a number of reactions including general weakness, heatwaves, palpitations, blurred vision, rhinorrhoea, feeling of suffocation, pruritus and urticaria (24).

### Where Tartrazine Can Be Found

Tartrazine is found in a wide range of foods and non food products. If you are intolerant of tartrazine you must check *all* food products before you buy them and ensure that medications are tartrazine free. You may find it useful in the early days to keep a food and health diary in which you record everything you eat (every single ingredient), how you are feeling and all products you have used. This will help you identify hidden forms of tartrazine more quickly.

### Food

This list is only a guide for the types of foods you need to check. Never assume a shop bought food is safe - always check the label and check it each time you buy the product as manufacturers do change the ingredients.

All forms of sweets (candies) Batter Battered Fish and Chicken **Biscuits Breads** Butter Cake Mixes Cakes **Candied Fruit Canned Fruit Canned Vegetables** Chewing Gum **Coloured Cheeses** Curries Gelatin Ice Cream

Jellies Macaroni Cheese Margarine Mavonnaise Mints Pasta Pastries **Pickles Powdered Soups** Pudding Desserts Salad Dressings Shrimp Smoked Fish Snacks: Potato and Corn Stews and Casseroles Yoghurt

### **Beverages**

Check all soft drinks - still and sparkling, full flavour and concentrated.

Some alcoholic drinks especially those using mixers and some forms of beer - if in doubt avoid a product until you have been able to confirm tartrazine content from the manufacturer.

Any form of processed fruit drink.

### Non Food

The biggest category of non food products that contain tartrazine are drugs - prescription and non prescription. Always check with your doctor and/or the pharmacist.

Other products that have been found to contain tartrazine include:

- Shampoo
- Cosmetics
- Lotions
- Toothpaste
- Vitamins
- Hair dyes
- Nail Polishes

You will also find that tartrazine finds its way into pet food which, depending on the severity of your sensitivity, may be a problem if you need to handle it. It may also be a problem for your pets.

### **Hidden Tartrazine**

You will need to become an additive detective to avoid tartrazine in all its forms. A few examples of hidden problems are given below. The keeping of a food diary will help you identify other problem areas.

- Curries: A trading standards swoop on restaurants in the West Midlands, known as Britain's 'Balti Belt', found that more than half of the most colourful dishes contained levels of additives that would breach safety rules under some circumstances, tartrazine was included (3).
- What you might think is candied peel is in some countries not real peel but rutabaga dyed with various colors including tartrazine
- No food can be seen as totally safe. Tartrazine has been found in foods you wouldn't ordinarily consider checking such as chocolate pudding and caviar.
- Boxed breakfast cereals there have been reports of tartrazine being used in the manufacture of the boxes.
- Certain eggs may be a problem as some forms of chicken feed have been found to contain tartrazine.
- Food recalls have included egg rolls, batter mixes, tortilla chips, and cheese.

# The Link to Aspirin

It has been frequently found that individuals with a sensitivity to aspirin also have a problem with tartrazine. For example:

- Sakakibara and Suetsugu found that around 15% of those with aspirin induced asthma also had a sensitivity to tartrazine (35).
- Four individuals, in a study of 47, with asthma associated with aspirin sensitivity reacted to challenge tests of tartrazine (23).
- Steinus et al found that in most cases where there was sensitivity to acetylsalicylaic acid (causing asthma) there was also sensitivity to tartrazine (42).
- Desmond et al noted that Tartrazine has been implicated in a variety of adverse reactions and that there is a high correlation between aspirin sensitivity and tartrazine sensitivity but that the reverse is exceedingly rare. They presented the case of an individual who had no problems with aspirin yet reacted adversely to tartrazine (8).
- Five hundred and four individuals with asthma or rhinitis underwent 1,868 oral challenge tests with analgesics, preservatives and food colorants. Sodium benzoate and other benzoic compounds, as well as tartrazine and other azo dyes, were found to give similar but milder adverse reactions than acetylsalicylic acid (aspirin) (32).

### **Diagnosis and Treatment**

Diagnosis of tartrazine sensitivity usually takes place after either a serious reaction leads to hospital investigations or because an individual suspects it has been a problem. As in many cases of food sensitivity identifying the culprit is not always a straightforward procedure.

If a severe reaction has taken place after consuming a particular food product then each of the ingredients will need to be tested to establish which is the problem agent.

Noticing that they react to only foods that have been coloured with tartrazine, many individuals have identified tartrazine as a problem without any form of testing.

It testing needs to take place it is usually in the form of oral challenges with varying doses of tartrazine (18).

Testing is effected by two factors:

- Doses producing adverse reactions range from minimal amounts up to 750 mg.
- And symptoms appear after periods of time ranging from minutes to 6 to 14 hours (1).

Both the above factors have been over looked, or not taken seriously enough, in many cases of testing. If you undergo a test and are told there you do not have a sensitivity but you believe that you do then keep a food diary and monitor your progress. You could of course choose to avoid tartrazine - with it being an ingredient that has no positive health benefits the only effect of avoiding it will have is to reduce the range of products available to you.

Dipalma, in 1990, states that dealing with this type of sensitivity is primarily a case of avoiding drugs and food products that contain tartrazine. There is no treatment available that will remove the sensitivity (10).

### **Questions and Answers**

# If tartrazine can cause all these problems why is it used in foods and medicines?

In some countries, including Norway and Austria, tartrazine is banned but in others it is still allowed for use probably because the number of reported instances of health problems has not, as yet, been seen as causing a big enough problem. Many doctors have expressed concern about its use in medications but most governments still do not recognise it is a sufficient problem to ban it.

# Why does tartrazine cause problems for some people and not others?

A specific answer to this question is not currently available. What we do know is that everyone, to some extent, has a unique biochemical make up and that means that we will vary not only in obvious features such as height and hair colour but also in how our bodies process and handle food and chemicals.

Remember that tartrazine is a chemical not a natural food and the body has to be able to process it and eliminate it. In some people the mechanism for removing it may not be as strong.

### Is there a test for tartrazine sensitivity?

There is no single standard test and you would be best discussing which type to undergo with your doctor. The most commonly used one is an oral challenge but the effectiveness of the test will depend on the dose used and the degree of sensitivity that you have. It is not uncommon for individuals to have negative results yet still be sensitive to tartrazine because of these dose related factors.

### Is tartrazine sensitivity an allergy?

Some studies believe they have identified reactions to tartrazine (IgE mediated) that would indicate the sensitivity is an allergy. Others have found no evidence that would indicate a classically defined true allergic reaction.

In many ways whether we classify tartrazine sensitivity as an allergy or intolerance problem is irrelevant. There is still no treatment, except for avoidance.

If your sensitivity is severe enough to be life threatening always use the term 'allergy' when explaining it to others as this will help impart the serious nature of your condition.

If your condition is not life threatening choose which label is most appropriate to you.

# Do I need to avoid all foods and products containing tartrazine?

If you have a severe sensitivity then you will need to avoid all products containing tartrazine. If your sensitivity is slight you may find that you can tolerate small amounts on an irregular basis but beware of exceeding your limit and giving yourself unwanted reactions.

### Will I always be tartrazine sensitive?

As far as I am aware no studies have been carried out long term to find out if individuals later develop a tolerance or not. There are some cases of children who have later been able to tolerate food colourings but if the condition develops in adults it is far less likely to go away.

### Do I need to avoid other food colours?

Many tartrazine sensitives also react to other food colours that have a similar chemical structure. Initially it may be necessary to avoid only tartrazine but you should monitor your health carefully and watch out for any return of unwanted symptoms. Using a food diary may help in identifying foods that have other suspect colours.

The colours that are often implicated are listed below (please not some of these have been banned in different countries):

E104 Quinloine Yellow E107 Yellow 2G E110 Sunset yellow FCF E120 Cochineal E122 Carmoisine E123 Amaranth E124 Ponceau 4R E127 Erythrosine E128 Red 2G E131 Patent Blue V E132 Indigo Carmine 133 Brilliant blue FCF E151 Black PN 154 Brown FK 155 **Brown HT** E160b Annatto, bixin, norbixin E180 Pigment rubine

#### What about other additives?

There is no reason to suspect that other additives will also cause problems. It is quite possible to be sensitive only to tartrazine but for some individuals there will also be problems with other food colourings and also other additives. For example, some tartrazine sensitive individuals have reported problems with BHT (Butylated hydroxytoluene E321) as well. It is possible that this is because, in some cases, one of its ingredients may be a coal tar derivative. It can be sprayed inside cereal boxes so can be a very hidden ingredient.

#### Do I have to stop using aspirin?

There are studies that show that some people who are sensitive to aspirin are also sensitive to tartrazine. It is not the case that those with only a tartrazine sensitivity will also have an aspirin sensitivity. If in doubt check with your doctor.

#### Will I also be sensitive to salicylates?

Salicylates occur naturally in many plant foods and are manufactured and appear in medicines (such as aspirin) and in

many products such as perfumes and cleaning fluids. Many salicylate sensitives also have a problem with artificial colours such as tartrazine (the chemical structure is similar). It is quite possible to be sensitive only to tartrazine and not react to any of the salicylates. If, however, you find that removing tartrazine and other artificial colours leads to a great improvement but then there is a relapse that is not linked with ingesting any colours you may find it useful to look at salicylates (information can be found in the library on the Food Can Make You III web site www.foodcanmakeyouill.com).

### **Appendix: Just What Is Tartrazine?**

The description below is taken from the "Code of Federal Regulations Title 21, Volume 1 Revised as of April 1, 2002 Sec. 74.705 FD&C Yellow No. 5"

### Definition

The color additive FD&C Yellow No. 5 is principally the trisodium salt of 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4- [4-sulfophenyl-azo]-1H-pyrazole-3-carboxylic acid (CAS Reg. No. 1934-21- 0). To manufacture the additive, 4-amino-benzenesulfonic acid is diazotized using hydrochloric acid and sodium nitrite. The diazo compound is coupled with 4,5-dihydro-5-oxo-1-(4-sulfophenyl)- 1Hpyrazole-3-carboxylic acid or with the methyl ester, the ethyl ester, or a salt of this carboxylic acid. The resulting dye is purified and isolated as the sodium salt.

**Tartrazine specification** or what you can expect to find within the dye:

- Sum of volatile matter at 135 [deg] C (275 [deg] F) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.
- Water-insoluble matter, not more than 0.2 percent.
- 4,4'-[4,5-Dihydro-5-oxo-4-[(4-sulfophenyl)hydrazono]-1Hpyrazol-1,3-diyl]bis[benzenesulfonic acid], trisodium salt, not more than 1 percent.
- 4-[(4',5-Disulfo[1,1'-biphenyl]-2-yl)hydrazono]-4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylic acid, tetrasodium salt, not more than 1 percent.
- Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl)hydrazono]-1H-pyrazole-3-carboxylate, disodium salt, not more than 1 percent.
- Sum of 4,5-dihydro-5-oxo-1-phenyl-4-[(4-sulfophenyl)azo]-1H-pyrazole-3-carboxylic acid, disodium salt, and 4,5dihydro-5-oxo-4-(phenylazo)-1-(4-sulfophenyl)-1Hpyrazole-3-carboxylic acid, disodium salt, not more than 0.5 percent.
- 4-Aminobenzenesulfonic acid, sodium salt, not more than 0.2 percent.

- 4,5-Dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3carboxylic acid, disodium salt, not more than 0.2 percent.
- Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1Hpyrazole-3-carboxylate, sodium salt, not more than 0.1 percent.
- 4,4'-(1-Triazene-1,3-diyl)bis[benzenesulfonic acid], disodium salt, not more than 0.05 percent.

4-Aminoazobenzene, not more than 75 parts per billion.
4-Aminobiphenyl, not more than 5 parts per billion.
Aniline, not more than 100 parts per billion.

Azobenzene, not more than 40 parts per billion.
 Benzidine, not more than 1 part per billion.

1,3-Diphenyltriazene, not more than 40 parts per billion.
 Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.
 Mercury (as Hg), not more than 1 part per million.
 Total color, not less than 87 percent.

http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edock et.access.gpo.gov/cfr\_2002/aprqtr/21cfr74.705.htm

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